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**NARCO BIO-SYSTEMS**

A HEALTHDYNE COMPANY

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**MANUAL**

FINAL REPORT

DEVELOPMENT OF ENGINEERING PROTOTYPE OF  
LIFE SUPPORT MODULE (LSM)

CONTRACT NAS 9-16723

Submitted to

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Lyndon B. Johnson Space Center  
Houston, Texas

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## 1.0 TECHNICAL REQUIREMENTS OF PROTOTYPE LIFE SUPPORT MODULE (LSM)

### 1.1 Technical Details

Each task item of the statement of work is presented below with a technical synopsis of the results.

#### "4.0 TECHNICAL REQUIREMENTS"

In order to provide basic life support capability, the following parameters and treatment capabilities are considered minimum. In addition, standard clinical specifications shall apply:

##### 1.1.1 "4.1 Electrocardiogram"

Frequency Response	Leads I, II, III: 0.35-45 Hz, minimum -3dB band width.
Input Impedance	10 megohms minimum at 60 Hz measured at electrode connector; 100 kilohms minimum at defibrillator paddles.
60 Hz Rejection	80 dB minimum with 5 kilohm source unbalance.
Leakage Current	Less than 20 ua maximum at 120V, 60Hz.(measured at patient cable inputs)
Defib. Protection	Circuit protection from voltages up to 5000 volts is provided at patient cable inputs.
Recovery Time	After defibrillation, ECG signal recovers within 1 second to linear range of ECG amplifier (recorder display sensitivity of 10mm/mv, 50-ohm resistive load).
Calibration	A 1mV +/- .05mV signal can be added to the ECG signal for calibration of the scope display or recorder.
Lead Selection	Leads I, II, III paddles and standard are selectable.
Lead OFF	Automatic detection of ECG lead off condition is signaled on the oscilloscope display.

#### 1.1.2 "4.2 Defibrillation"

Energy Level	Eight discrete levels of -5, 10, 25, 50, 100, 200, 300, and 360 joules (standardized against a 50-ohm load) are selectable. Continuous tone and paddle lamp indicate when selected energy level reached. Energy level is refreshed whenever stored energy drops below a preset threshold.
Discharge Switching	Simultaneous depression of pushbutton switches in paddles required. Stored energy can be discharged without a patient load through the test load or by disarm without damage to defibrillator.
Charge Time	Less than 8 seconds to 360 joules.
Disarm Capability	Automatic disarm after 30 seconds or after power-down. Manual disarm via front-panel switch.
Electrode Contact	Standard paddles provide a minimum of 50 square cm. electrode contact area for adult use. Pediatric-sized paddles and internal paddles are also available.
Energy Tester	Fifty ohm test load senses energy. LED flashes to indicate satisfactory performance.
Pulse Waveform	Edmark (critically damped LRC).
Mode Selection	The normal operating mode is emergency ventricular defibrillation (non-synchronized). Defibrillator is in emergency mode when turned ON. Switch activation selects the synchronized cardioversion mode. Defibrillator reverts to emergency mode if QRS event not detected for period greater than three seconds.

#### 1.1.3 "4.3 Resuscitation"

Inlet Pressure	140 to 620 kPa (20 to 90 psi).
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Temperature -40°C to 100°C (-40°F to 212°F)

Flow 85 lpm at 140 kPa to 350 lpm at 620 kPa (approx.). Inspiratory effort at 345kPa: 50mmH2O +/- 15 Pa to start flow, flows lpm at 220 PaH2O +/- 20mm Pa straight line curve to maximum flow.

Pressure range and limit to pulmonary system: 0-40mm Hg. Maximum escape volume before pressure equalization when charging.

Valve 45 ml.

Filtration 4 micron sintered stainless steel, effective filtration area .94 in<sup>2</sup> (6.0 cm<sup>2</sup>).

Weight 3.5 oz (99g)

Materials "Noryl" plastic, polyester, polycarbon, Metal: moving and adjusting parts are all stainless steel: fastening parts are steel, brass, and aluminum which are plated for corrosion resistance. Rubber parts are all silicone except hose.

Corrosive-ness NONE

Hose Burst Pressure 1,000 psi (70 kg/cm<sup>2</sup>).

Hose Fittings DISS, 'O' rings for finger tightening.

Downstream Housing 22 mm O.D. x 15 mm I.D.

#### 1.1.4 "4.4 Blood Pressure"

ON/OFF Two position slide switch.

"ON" Normal operation - allows monitor to cycle on pre-programmed time intervals.

"OFF" Standby mode, no cycling occurs, data retained.

START/STOP	<p>Pushbutton depressed to begin manual blood pressure measurement if none in progress. Overrides present cycle time, and resets timer.</p> <p>If depressed during blood pressure measurement, unit will abort cycle.</p>
AUDIO	Audible tone indicates start of a cycle or an error code has been obtained.
Measure- ment Ranges	Heart Rate: 40 to 180 bpm; pressure 70 to 270 mmHg for systolic, 40 to 150 mmHg for diastolic, and 50 to 180 mmHg for mean arterial values. Monitor is designed to operate between 40 to 280 mmHg. Clinical test have verified accuracy in accordance with proposed AAMI standards.
Pressure Measure- ment Method	Auscultation method when Korotkoff sounds are audible, with a back-up method of oscillometry when Korotkoff sounds cannot be heard.
Automatic Measure- ment Intervals	Physician may adjust time interval from six minutes minimum to 60 minutes maximum, by preprogramming RAM PACK. These cycles can be pre-programmed to change during the day and night to more frequent or less frequent time intervals.
Measure- ment Cycle Time	Typically 20-50 seconds; cuff inflated to pressure mmHg for no longer than 90 seconds.
Maximum Cuff Pressure	300 +/- 10 mmHg
Autozeroing	Pressure transducer channel automatically zeroed before each reading.
Artifact Rejection	Microprocessor program discriminates between pressure signals and extraneous sounds, such as patient movement.

Cuff Inflation/Deflation	Automatic, motor driven pump operation. Deflate rate under microprocessor control.
Data Storage System	Nonvolatile CMOS 2K RAM, located in battery pack. Information retained until batteries are replaced. Timing of events provided by real time clock in battery pack.
Digital Display	3 digit, 7 segment, liquid crystal display. Systolic, diastolic, and heart rate information to be alternately displayed. Blinking cursor provided to indicate when unit is ON.
Patient Safety	Measurement cycle under 90 second timing control. Pneumatic system opened when OFF. Air harness detachable at cuff. Independent over pressure sensor to interrupt system at 300 mmHg 510K approval.
Power Requirement	Replaceable battery pack consisting of six C-size, non-rechargeable batteries.
Dimensions	8.60" L x 4.75" W x 1.95" D
Weight	Monitor, vinyl bag and batteries - 3 lbs. 9 oz.

1.1.5 "4.6 Oral Temperature"

Length	91 millimeters
Width of Sensor Matrix	9 millimeters
Temperature Range	Fahrenheit thermometer: 96.0° to 104.8° Centigrade thermometer: 35.5° to 40.4°
Temperature Increments	Fahrenheit thermometer: 0.2° Centigrade thermometer: 0.1°
From One Dot to the Next	
Matrix Arrangement	Fahrenheit thermometer - Two arrays one of 4 rows x 5 dots measure temperatures from 96.0° to 99.8°, the other of 5 rows x 5 dots measures

temperatures from 100.0° to 104.8°  
Centigrade thermometer - Two arrays  
one of 5 rows x 5 dots measures  
temperatures from 35.5° to 37.9°; the  
other of 5 rows x 5 dots measures  
temperatures from 38.0° to 40.4°.

#### 1.1.6 "4.7 Drug Kit"

The following drugs were provided as Government  
Furnished Equipment to Narco and were packaged into the  
prototype LSM:

Sodium Bicarbonate, 50ml  
Epinephrine, 1mg in 10 ml  
Calcium chloride, 1 gram in 10 ml  
Atropine, 1 mg in 10 ml  
Lidocaine, 100 mg in 5 ml  
Isoproterenol, 1 mg in 5 ml

#### 1.1.7 "4.8 Aspirator"

Supply Pressure	40 to 90 psig(275-620 kPa)
Suction Pressure	407mmHg minimum at 50 psig(345 kPa)

The aspirator has been modified to incorporate a  
suction pressure regulator which can control the  
suction pressure.

Flow Suction	15 LPM minimum at 50 psig(345 kPa)
Inlet Fitting	Standard Diameter Index Safety System, 562 x 18 external thread
Filters	65 micron(1.6 micrometers) sintered bronze (replaceable)
Finish	Clear anodized aluminum

### 1.2 Subsystem Operation

#### 1.2.1 PF III and Accessories

Patient ECG monitoring can be accomplished with  
either the standard external defibrillator  
paddles or separate patient electrodes. The  
following paragraphs provide descriptions of  
electrode application methods and suggested  
monitoring techniques.



#### 1.2.1.1 Application of Electrodes

When the patient's ECG is monitored by separate patient electrodes, use the recommended disposable electrodes for best results. For proper operation, the electrodes must be the electrochemically-reversible (silver/silver chloride) type. Pregelled electrodes are often preferred.

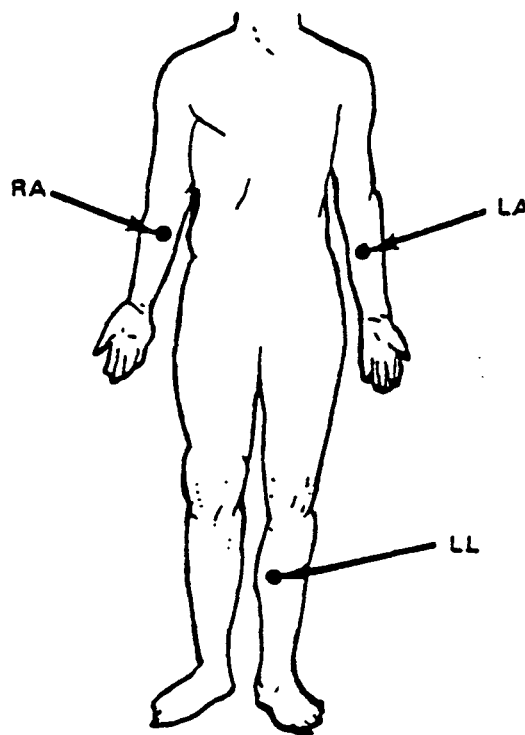
#### CAUTION

To insure proper electrode operation, store the electrodes in a manner to prevent evaporation of the gel. Do not remove the backing paper from the electrodes unless they will be used immediately. Loss of electrolyte on pregelled electrodes often occurs due to improper storage or inattention to the manufacturing date and shelf life.

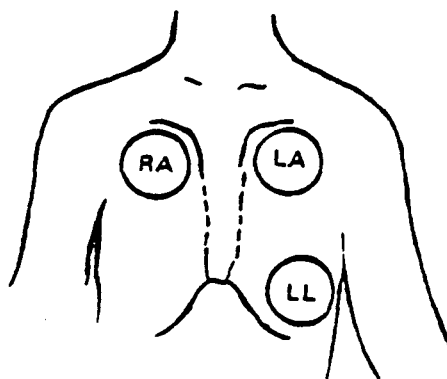
While the attachment of electrodes to the patient is a simple process; signal distortion, noise, and skin-potential artifact effects can result if the attachment is improperly done. Prepare the electrode sites identified in Figure 5-1 by cleaning the skin with an alcohol-soaked gauze and continue to rub until the skin is red. Remove the protective paper from the adhesive-backed pad, then press the electrode in place on the prepared skin site. the exact location can be modified somewhat to avoid regions which do not hold electrodes well. The limb lead configuration may be used whenever chest leads are undesirable.

#### WARNING

Apply electrodes away from desired paddle application sites to prevent accidental electrode/paddle contact during emergency defibrillation.



LIMB LEAD CONFIGURATION



CHEST LEAD CONFIGURATION

Figure 1-1

ECG Electrode Placement

Attach the patient cable lead wires to the electrodes. The lead wires are color-coded in accordance with American Heart Association standards, as follows:

ELECTRODE	LEAD WIRE COLOR
RA	White
LL	Red
LA	Black

#### 1.2.1.2 Patient Monitoring Procedure

- a) Turn ON the unit by pressing the power ON switch. select the desired lead position I, II, or III. (II is most often used and is automatically selected at turn ON)
- b) Verify that the ECG electrodes and patient cable are connected as just described.
- c) Use the ECG size switches to obtain an appropriate display.
- d) When monitoring from the paddles, the negative (sternum) paddle is applied just to the right (patient's right) of the upper sternum below the clavicle; the positive (apex) paddle is applied to the left (patient's left) of the cardiac apex (below left nipple and under breast). (See Figure 5-2). When positioned in this manner, the ECG signal from the chest is normally upright.
- e) The scope display can be "frozen" for detailed inspection or printout. Press the FREEZE switch to hold the trace; press the switch again to return the scope to real-time display.
- f) While the scope display is frozen, ECG lead, ECG size, and recorder speed are not changeable. The frozen trace can be transferred onto a strip-chart by turning on the recorder until all of the trace is recorded. The frozen trace will move from the scope onto the recorder automatically after a 2 second delay to allow heating of the recorder stylus.
- g) For an audible "beep" with each QRS detection, press the QRS VOLUME switch. Press the switch again for a louder "beep."

A third press of the QRS VOLUME switch will turn the "beep" tone OFF.

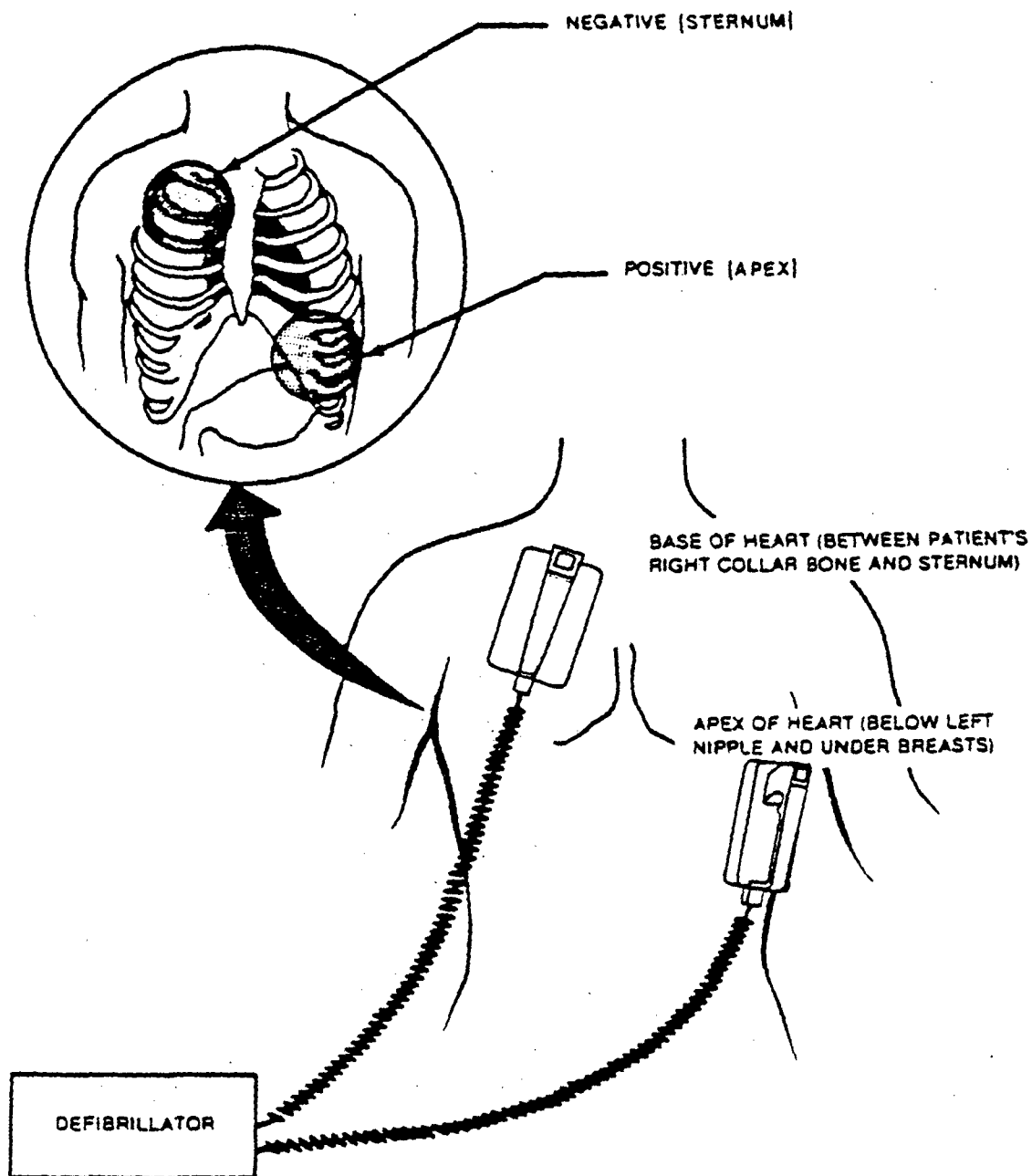


Figure 1-2  
Defibrillator Paddle Location

### 1.2.1.3 Patient Monitoring Problems

Figure illustrates typical monitoring problems and the resultant scope displays. These problems are discussed in the following paragraphs.

Power Line Interference (Figure 1-3) - It is possible to get power line interference on the scope trace if it is used in areas where the electromagnetic fields are extremely strong. Keeping the patient cable lead wires together will help minimize this interference.

Electromyographic (EMG) Interference (Figure 1-3) - This problem may be generated when the active electrodes are placed over skeletal muscles that are being contracted. EMG interference is best eliminated by careful selection of electrode sites to provide isolation from large, often used, muscles. Keeping the patient relaxed and almost motionless will also help to eliminate this interference.

Intermittent Trace (Figure 1-3) - Possible causes of an intermittent trace include a disconnected electrode, dry or intermittent electrode, open patient cable lead wire, or a disconnected patient cable. Moving the cable and shaking the electrodes will often identify the cause of the problem.

Motion Artifacts and Triboelectric Noise (Figure 1-3) - Motion artifacts are commonly encountered in a moving ambulance. These are usually generated at the electrode/skin site and are distinguished from EMG interference since they may be caused by any motion of the patient and not just muscular activity. Motion artifacts can be reduced by using the recommended electrodes and good electrode site preparation techniques. Prevent the rubbing of objects against the electrodes and tie down the patient cable to the patient or stretcher. Triboelectric noise is caused by the generation of discharge of static electricity. This noise is most often generated near the electrode sites in low humidity environments by motion of a variety of type of clothing or objects. Although it resembles motion artifact interference on the trace, it is usually caused by motion of a static field around the patient (i.e., motion of charged bedclothes, uniforms

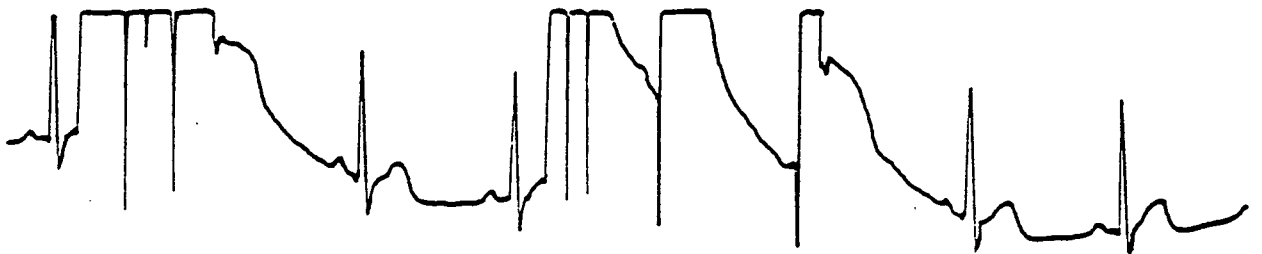
or plastic appliances). Triboelectric noise can be reduced by using the recommended electrodes and good electrode site preparation techniques.



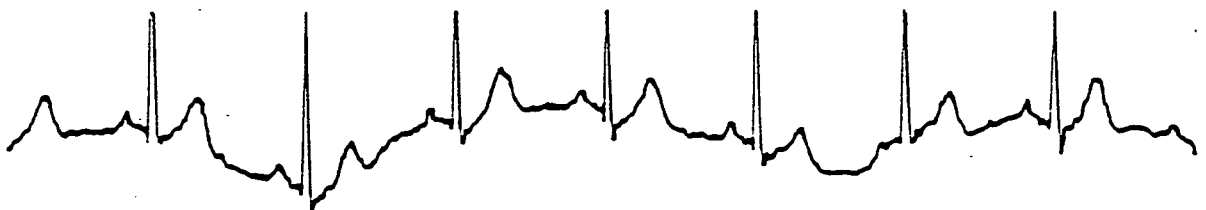
(a) Power line interference



(b) EMG interference



(c) Intermittent Trace



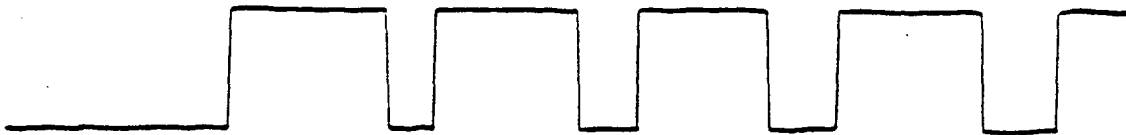
(d) Motion artifact and triboelectric noise

#### TYPICAL MONITORING PROBLEMS

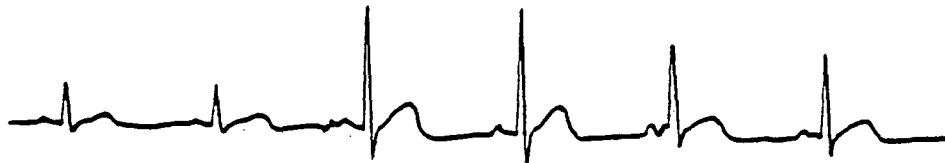


#### 1.2.1.4 Typical Waveforms

Figures illustrate typical waveforms that will be observed under several operating conditions. These include the electrode and paddle monitoring configurations and a typical ECG trace recovery after reattachment of a loose lead.



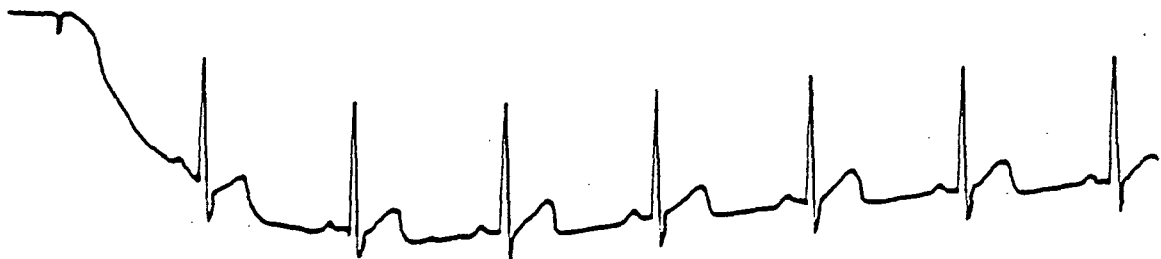
(a) Cal signal, STD lead



(b) ECG, leads I, II, and III



(c) ECG from defibrillator paddles



(d) Reattachment of a loose lead

Figure 1-4  
TYPICAL WAVEFORMS

#### 1.2.1.5 Setting of Heartrate Alarms

At power up, the lower and upper rate alarm limits are initialized to 40 and 120 bpm, respectively. The upper and lower limits may be independently adjusted in increments or decrements of 5 bpm. The range of the upper alarm limit is 255 to the setting of the lower alarm limit +5bpm. The range of the lower alarm limit is 30 to the upper alarm limit -5bpm. Overlapping of alarm limits is electronically prevented.

To set the alarm limits, press the alarm limit UPPER/LOWER switch. The digital heart rate display will be replaced with one of the current alarm limits identified with either a "U" or "L" for the upper or lower limit; respectively. If the limit displayed is not the desired one, press the UPPER/LOWER limit switch again to display the opposite limit. If either of the limit and switches is briefly pressed, the displayed limit changes by 5bpm. If either switch is pressed and held, continuous change of the limit occurs until the limit is at one end of its range. If none of the switches is pressed for a five second period, the digital heart rate is again displayed replacing the heart rate limit. However, the upper and lower limits as well as the current heart rate are always visible at the right side of the scope display.

For the alarm limits to be enabled, the alarm ON/OFF switch must be pushed. A green indicator above the switch will light to signal that the alarm is active. To turn OFF the alarm, press the alarm ON/OFF switch.

#### 1.2.1.6 Clock/Timer

The current time (hours and minutes) is normally presented on the scope display. If elapsed time is desired, press the CLOCK/TIMER switch. The clock display is replaced with a running timer beginning at 00:00. The timer provides elapsed time up to 100 minutes. Pressing the CLOCK/TIMER switch again cancels the timer and changes the display back to the current time.

If the SETCLK message appears on the time display, something has occurred which has caused the clock to lose track of time. The

battery used to power the clock may need to be replaced. To set the current time in the clock, the following procedure is used.

- a) Press and hold the CLOCK/TIMER switch.
- b) When 5 seconds has elapsed, the scope display will show clock month as "MO xx", where xx can be 01 to 12, January through December. By pressing the 50mm switch, the month can be advanced as desired.
- c) Again press the CLOCK/TIMER switch. The scope display now shows the clock day as "DA xx", where xx can be 01 to 31. The 50mm switch is used to set the current day.
- d) Again press the CLOCK/TIMER switch. The scope display now shows the clock hour as "HR xx", where xx can be 00 to 23, 12AM to 11PM, respectively. The 50mm switch is used to set the current hour.
- e) Again press the CLOCK/TIMER switch. The scope display now shows the clock minutes as "MT xx", where xx can be 00 to 59. The MT indicates that tens digit can be set with the 50mm switch.
- f) Again press the CLOCK/TIMER switch. The scope display now shows "MU xx", where MU indicates that the units digit of minutes can be set with the 50mm switch.
- g) Press the CLOCK/TIMER one last time to have the newly set time displayed on the scope (seconds, although not displayed, are set to 00).

If at any time during the clock set procedure, neither the CLOCK/TIMER nor the 50mm switches are pressed for 60 seconds, the scope display will automatically revert back to the current time.

#### 1.2.1.7 Recorder Documentation

The strip chart recorder provides an annotated record of the ECG signal. When the recorder is turned ON, the selected defibrillator energy, heart rate, ECG Lead, ECG size, recorder speed, month, day, and time of day are printed at the top of the chart paper (Refer to Figure 1-5). The information is repeated every 10 seconds as

long as the recorder is running.

The selected defibrillator energy may be 5J, 10J, 25J, 50J, 100J, 200J, 300J, or 360J. If no energy has been selected, this parameter is omitted. The heart rate printed is the current 4 beat average.

The ECG Lead may be I, II, III, PDL, or STD. The ECG size may be G4, G7, G10, G15, or G20 for a gain size of 4, 7, 10, 15, or 20mm/mv. The recorder speed may be S25 or S50 for 25 or 50mm/sec respectively. While the recorder is running and the selected defibrillator energy, ECG Lead, ECG size, or speed is changed, the new condition will be printed out on the chart paper at the time that it occurs.

When the AUTO switch is pressed, the AUTO indicator above the switch comes ON. In the AUTO mode the recorder will turn ON and run a 10-second strip when either of the heart rate alarm limits are exceeded (the heart rate alarm must be turned ON). Pressing the AUTO switch again cancels the auto mode.

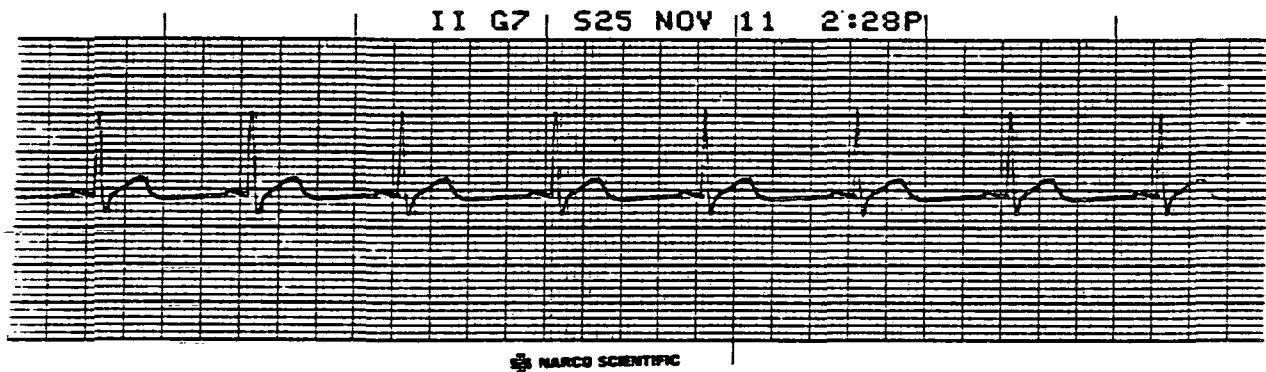


Figure 1-5

#### STRIP CHART RECORDING

##### 1.2.1.8 Defibrillation

#### CAUTION

Defibrillation should be performed only by qualified medical or paramedical personnel trained in the proper operation of this instrument.

## WARNING

These instructions do not supersede established medical procedures or staff preferences concerning patient care. "Best practice" as determined by the medical community is always to be observed.

The normal operating mode for the defibrillator is emergency (non-synchronized) defibrillation. Abbreviated instructions for performing emergency defibrillation are provided on the label on top of the monitor/defibrillator. The front panel and defibrillator paddle controls are clearly labelled in the numerical sequence of their operation. A more detailed version of the procedure follows.

### 1.2.1.9 External Defibrillation Procedure

- a) Connect the standard external paddles to the unit.
- b) Apply gel over the entire conductive surface of each paddle.

## WARNING

An excessive amount of conductive gel can result in a short circuit between paddles during defibrillation. This will reduce the delivered current and adversely affect the probability of successful defibrillation.

- c) Turn ON the monitor/defibrillator by pressing the POWER ON switch. Observe that the ON indicator lights.
- d) Select the desired delivered energy setting. The indicator above the selected setting will begin to flash.

## WARNING

The delivered energy required for successful emergency defibrillation may vary with the size, weight, and age of the patient. The formula for determining the emergency setting must be defined by the responsible medical facility.

If charging is not initiated within 2 minutes after an energy level is selected, the selected energy level is cancelled.

- e) Momentarily press the CHARGE switch (either on the front panel or on the side of the APEX panel). Observe the energy select display and verify that the proper energy storage level is obtained. An audible tone sounds and the READY indicator on the STERNUM paddle lights when the selected level is reached.
- f) Position paddles for defibrillation. Refer to Figure 1-6.

#### WARNING

Chest burns to the patient can result from multiple high-energy discharges if poor contact between paddles and skin occurs. Poor contact can result from chest deformities, inadequate downward pressure during defibrillation or insufficient amounts of conductive solution or gel placed between paddles and skin.

To discharge the defibrillator simultaneously, press both firing buttons on the paddles.

#### WARNING

For operator safety, handle the paddles carefully and do not touch metal surfaces of the paddles or the patient during discharge. The paddles should be kept clear of ECG or other electrodes or metal parts in contact with the patient.

Repeat steps (d) through (g) as required. Any stored energy in the defibrillator can be safely discharged internally by activation of the defibrillator DISARM switch.

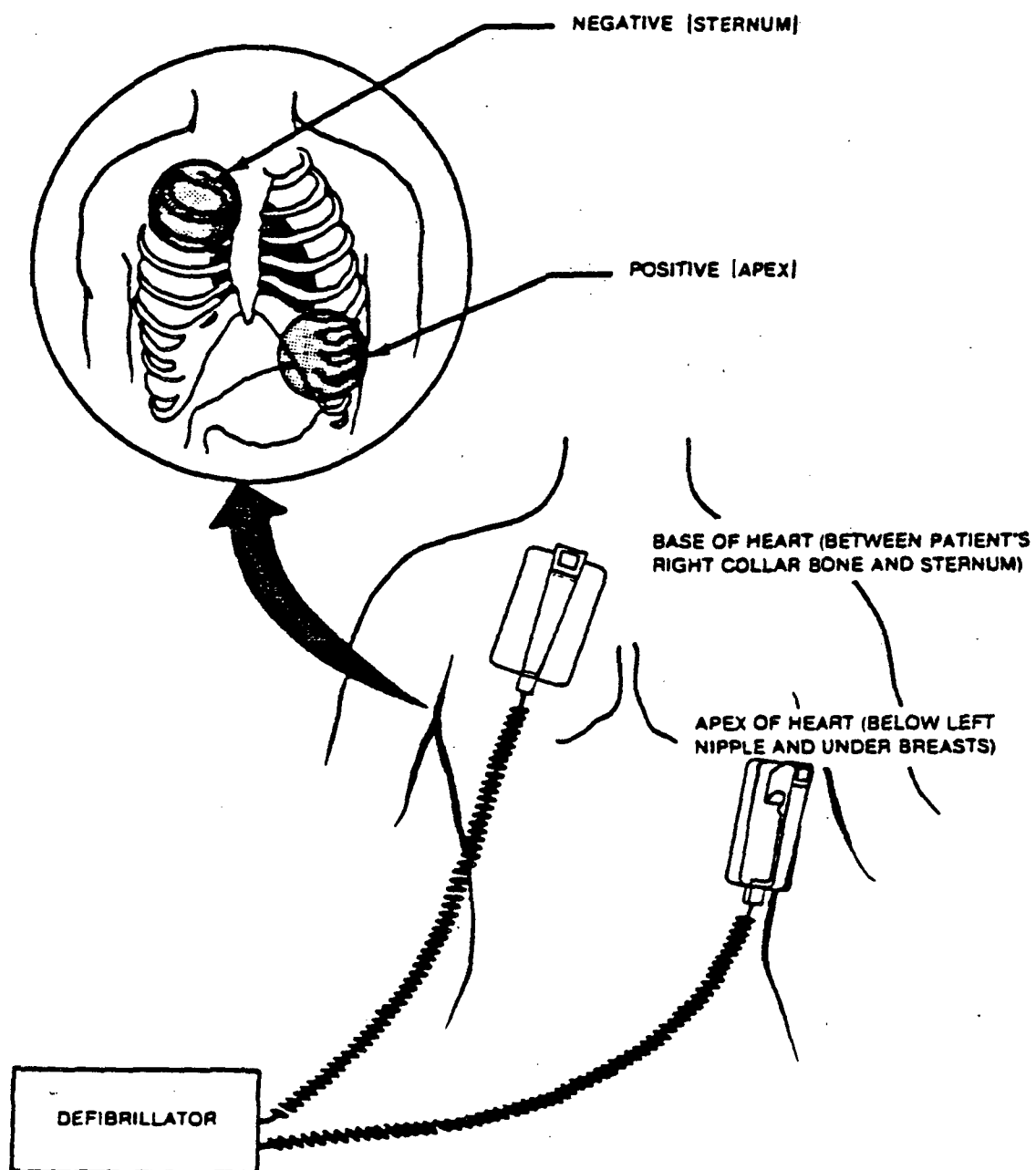


Figure 1-6  
DEFIBRILLATOR PADDLE LOCATION

The scope display will blink at defibrillator discharge.

If the defibrillator is not discharged within 30 seconds after charging is initiated, the defibrillator disarms by discharging the stored energy internally. The energy level will remain selected for up to 2 minutes after discharge and will then automatically deselect.

#### 1.2.1.10 Internal Defibrillation Procedure

- a) With the monitor/defibrillator turned OFF, connect the internal paddle handle assembly to the unit.
- b) Screw the appropriate size of internal paddle spoons into the handles until tight and prepare the spoon surfaces.
- c) Turn ON the monitor/defibrillator by pressing the POWER ON switch. Observe that the ON indicator lights.
- d) Select the required delivered energy setting, up to a maximum of 50 joules. The indicator above the selected setting will begin to flash.

#### NOTE

The defibrillator will not charge above 50 joules when internal paddles are connected.

If charging is not initiated within 2 minutes after an energy level is selected, the selected energy level is cancelled.

- e) Momentarily press the front panel CHARGE switch. Observe the energy select display and verify that the selected level is obtained. An audible tone sounds when the proper energy level is reached.
- f) Position paddles for defibrillation.

#### WARNING

For operator safety, handle the paddles carefully. DO NOT touch metal surfaces or the patient during discharge. The paddles should be kept clear of ECG or other electrodes or metal parts in contact with the patient.



### WARNING

If the indicated energy level exceeds 50 joules, DO NOT use the defibrillator.

- g) Discharge the defibrillator by pressing the INTERNAL PADDLE DISCHARGE front panel switch. If the defibrillator is not discharged within 30 seconds after charging is initiated, the defibrillator disarms. The stored energy is then dissipated internally.
- h) Repeat steps (d) through (g) as required. Any stored charge in the defibrillator can be safely discharged internally by the defibrillator DISARM switch.

#### 1.2.1.11 Synchronized Cardioversion

Synchronized cardioversion may be required as part of specific procedures to treat arrhythmias.

- a) Connect the ECG electrodes and patient cable as described in Section V.
- b) Connect the external paddles to the unit.
- c) Apply gel over the entire conductive surface of each paddle.

### WARNING

An excessive amount of conductive gel can result in a short circuit between paddle during defibrillation. This will reduce the delivered current and adversely affect the probability of successful defibrillation.

- d) Turn ON the monitor/defibrillator by pressing the POWER ON switch. Observe that the ON indicator lights.
- e) Select the desired ECG Lead.
- f) Momentarily press the SYNCHRONIZER switch and observe the indicator lights.
- g) Observe that the marker pulse occurs at the desired point of the ECG waveform. The synchronizer indicator will blink off with each QRS detection.

- h) Select required delivered energy. The indicator above the selected setting will begin to flash.

#### WARNING

The delivered energy required for successful cardioversion may vary with size, weight, and age of patient. The formula for determining the appropriate energy level must be defined by the responsible medical facility.

- i) Momentarily press the CHARGE switch on the front panel or on the APEX paddle. Observe the energy select display and verify that the selected energy level is obtained. An audible tone sounds and the READY indicator on the STERNUM paddle lights when charging is complete.
- j) Position paddles for defibrillation. Refer to Figure 1-6.

#### WARNING

Chest burns to the patient can result from multiple high-energy discharges if poor contact between paddles and skin occurs. Poor contact can result from chest deformities, inadequate downward pressure during defibrillation or insufficient amounts of conductive solution or gel placed between paddles and skin.

- k) Press the paddle firing switches after noting a satisfactory synchronizer marker position on the ECG waveform. The defibrillator is automatically discharged at the time, and the patient's QRS complex indicated by the synchronizer marker. The scope display will blink at defibrillator discharge.

#### WARNING

The defibrillator will discharge within 35 msec of the marker pulse when fired. Carefully observe the position of the marker pulse relative to the patient's QRS and T waves before deciding to administer a charge for elective cardioversion. **IMPROPER CARDIOVERSION ATTEMPTS CAN CAUSE VENTRICULAR FIBRILLATION!**

- l) The defibrillator will automatically revert to the emergency mode if no QRS is detected for a period greater than three seconds. The defibrillator will not discharge during this transition from synchronized to emergency mode even though both paddle switches are depressed at this time.
- m) Selecting a new ECG lead will cancel the synchronized mode. The synchronized mode cannot be selected with an ECG signal input from the defibrillator paddles - a patient cable/electrode input is required.

#### 1.2.1.12 Arrhythmia Detector

The arrhythmia detector is enabled by selecting Heart Rate Alarms "ON." No further operator input is required. When the number of detected arrhythmia events exceeds a pre-determined level, the Heart Rate alarm tone will sound, recognizable as an alternating tone. In addition, the alarm condition will be indicated on the CRT as follows:

- a) If the alarm condition is a heart rate outside of the set limits, then a letter will appear on the CRT between the indication of selected ECG Lead and the indication of present heart rate. This letter will be an "H" for a high heart rate or an "L" for a low heart rate. The alarm indication will persist until manually shut off or the heart rate returns to within the set limits.
- b) If the alarm condition is an arrhythmia count out of limits and there is no heart rate alarm, then the alarm tone will sound and the letter "A" will appear as above. The alarm condition indication gives priority to displaying heart rate before arrhythmia. The alarm tone will sound for any out-of-limit condition.

The arrhythmia counter can be rapidly reset to zero by briefly turning the heart rate alarms OFF. This is a convenient procedure to cancel inputs due to artifact or other anomalies.

A detailed discussion of the system operating details, including the selection of the arrhythmia count trigger level, can be found in

the Appendix.

#### 1.2.2 Positive-Pressure Resuscitator

Resuscitation is accomplished using the Elder Demand Valve with face mask.

To resuscitate a non-breathing patient, the Elder Demand Valve is designed for use with a face mask, endotracheal tube, esophageal airway, or tracheostomy tube. When connected to the breathing system of a non-breathing patient with one of these modes, oxygen will flow to the patient and inflate the lungs when the manual button is depressed. Only enough effort should be applied to the button to ensure a normal movement of the chest. The resulting pressure will be maintained until the manual control is released. Passive exhalation then takes place through the non-rebreathing valve.

The Elder Demand Valve is also used to ventilate a patient in conjunction with Cardiopulmonary Resuscitation (CPR).

##### Operation

- a) Connect the pressure hose to an oxygen supply source capable of delivering 140 to 620 kPa (20 to 90 psi) to the Elder Demand Valve and turn oxygen supply to ON.
- b) Apply the Valve with one of the designed modes to the airway entry and tilt the head back.
- c) If no inflation of the lungs occurs, an obstruction to air passages should be suspected. Such an obstruction must be cleared before ventilation can be effective.
- d) Press the manual button until the chest rises to ventilate, then release the button to allow passive exhalation to occur. The breathing cycle of an adult is 12 to 15 times per minute, 15 to 20 for children, and 25 to 35 for infants.

#### 1.2.3 Aspirator

Establish the need for aspiration prior to resuscitative efforts. A minimum amount of time should expire prior to initiating resuscitative efforts. Generally, observation of the patients

mouth will indicate the need for aspiration.

- a) Connect the hose to an oxygen supply capable of delivering 40 to 90 psig (275-620 kPa) to the Robertshaw Aspirator and SLOWLY turn ON the oxygen supply. After the initial SLOW opening, the valve should be fully opened.
- b) Open the patients mouth and carefully insert the aspirating tip of the catheter. Use gentle stroking motions - DO NOT JAB.
- c) Depress the Aspirator Control Button.
- d) Care should be taken not to invert the jar so that fluid will not enter the venturi system.

With inlet pressure applied to the aspirator and the aspirator control button depressed, oxygen will flow through the aspirator venturi system causing a negative pressure (suction) in the aspirator jar and the catheter.

A positive pressure can be applied to the aspirator to remove stubborn mucus plugs or for partial emergency emptying of an overfilled aspirator jar by covering the aspirator orifice with a finger. During the positive pressure cycle, oxygen under pressure flows through the aspirator jar and out through the tip of the catheter.

The standard aspirator has been modified to include a suction pressure regulator. As stored, the regulator body should be screwed fully clockwise as viewed from above. This seats the regulator ball firmly against the valve seat and defeats the suction regulator. Maximum suction pressure will be developed in this condition. To reduce the suction, turn the regulator body counter-clockwise until the suction pressure is established at the desired level.

#### 1.2.4 Blood Pressure Measurement

See detailed Instruction Manual included in the Appendix.

#### 1.2.5 Oral Temperature Sensors

- a) Remove thermometer from wrapper. Peel back paper wrapper to expose handle end of

thermometer. Remove thermometer, taking care not to touch sterile indicator dots or shaft as these will go in patient's mouth.

- b) Place thermometer under tongue. Insert thermometer under tongue as far back as possible into either heat pocket. Have patient press tongue down on thermometer, keeping mouth closed.
- c) Remove after 45 seconds.
- d) Read temperature. Wait a few seconds for the dots to stabilize. The last blue dot gives you the patient's temperature.
- e) Attention to proper useage - because the Tempa-DOT Ready Strip Thermometer is highly sensitive, failure to register accurate temperature may result from:
  - 1. Improper placement in the mouth. Be sure to place the thermometer at the base of the tongue as far back as possible on either side.
  - 2. Failure of patient to keep mouth closed for at least 45 seconds without displacing the thermometer by movement of tongue.
  - 3. Failure to allow 45 seconds for the sensor matrix of the thermometer to come into equilibrium with the tissue surrounding it.
  - 4. Exposure to cold weather, smoking, eating, or drinking. Wait for at least 15 minutes before inserting thermometer so that mouth temperature may stabilize.

In rare instances, a dot may not "fire." Always read the last dot that has fired - or changed to blue - as the correct temperature.

## 2.0 EQUIPMENT SELECTION AND DESIGN CRITERIA FOR THE BLOOD PRESSURE MEASURING SYSTEM

A thorough evaluation of existing blood pressure measuring devices was performed. The criteria used for the evaluations was established through consideration of reliable performance and minimal operating requirements. Only existing blood pressure devices were reviewed for the Life Support Module. Each device was judged by the same

criteria.

## 2.1 Design Criteria

The design criteria selected for evaluating the blood pressure devices included:

- . Non-invasive Measurements
- . Standard Mode of Operation
- . Adequate Data Storage
- . Automatic Operation
- . Portability

These criteria were selected from overall consideration of reliable performance and minimal operating requirements.

### 2.1.1 Non-invasive Measurements

The main objective for choosing non-invasive measurements as a criteria was patient safety. Although problems such as coagulation have become less severe through the use of appropriate drugs, there still exists several disadvantages with invasive pressure measurements. Among the disadvantages are the difficulties associated with the insertion of the catheter into either the ulnar or radial artery. Usually, the occlusion of one artery will not compromise the blood supply to the hand; however, the tissue exclusively supplied by the occluded artery becomes ischemic. Arterial catheter lines can become disconnected, air bubbles in the fluid-filled pressure lines and thrombus formation are all possible complications.

Many studies have been performed on the accuracy of invasive vs non-invasive measurements. The deviation was small enough (usually within 10%) that the method of measuring blood pressure non-invasively has been widely accepted. The complexity of operating a non-invasive blood pressure device compared to an invasive pressure device is significantly reduced. This is due to simpler equipment (connecting an arm cuff with velcro compared to inserting a catheter into an artery) and very few precautionary steps need to be taken. Patient safety is extremely

important in space due to the lack of medical back-up facilities.

Non-invasive pressure measurement was chosen as a major criterion. Following the overall objectives of reliable performance and minimal operating requirements; non-invasive measuring techniques insure greater patient safety and simpler equipment to work with while using a commonly accepted method for making blood pressure measurements.

#### 2.1.2 Standard Mode of Operation

Two measuring techniques are considered as the standard modes of operation when taking blood pressure non-invasively. These two modes are the auscultatory method and the oscillometric method. Other modes, such as Doppler techniques, have a significant increase in operating requirements and are generally more susceptible to motion artifacts.

The auscultatory method is based on the sounds of Korotkoff. A blood pressure cuff is inflated around the upper arm until the brachial artery remains collapsed. As the cuff pressure is gradually reduced, the pulsations are heard through a stethoscope placed over the brachial artery at the antecubital space. When the first pulsation is heard, the pressure level indicated by the manometer connected to the cuff is the systolic pressure. When the last pulsation is heard, usually a muffled sound, the level indicated by the manometer is the diastolic pressure. The accuracy of the auscultatory method for measuring systolic and diastolic pressures is usually within ten percent of direct arterial measurements.

The oscillometric method is used when the Korotkoff sounds are faint or cannot be heard from the forearm artery. This is especially useful in young children or patients in shock. The oscillometric method is often used as an accessory method for estimating arterial pressure in such cases. This method is also viewed as a quick, accurate way of determining mean pressure. The oscillometric mode is based on the pressure pulsations registered in an inflated blood pressure cuff around the forearm. As the pressure of the cuff is gradually reduced, the pressure pulsations grow in amplitude. The maximum amplitude of



pulsation is assumed to occur at the mean pressure. Generally, the oscillometric version of systolic and diastolic pressures is based on calculated values and is not as accurate as the auscultatory version. The mean pressure; however, is very accurate since the largest oscillometric pulsation is read directly as the mean pressure. In the auscultatory mode, the mean pressure cannot be measured, but is approximated with a mathematical formula using the measured systolic and diastolic pressures.

Both the auscultatory and the oscillometric modes of non-invasively measuring blood pressure are considered valid techniques. The auscultatory method is more accurate for measuring systolic and diastolic pressures. The oscillometric method is used as a backup and is an accurate means of measuring mean blood pressure.

#### 2.1.3 Adequate Data Storage

Each blood pressure measurement is useful as an indicator of immediate problems and as an integral part of a trend analysis. The blood pressure instrument used in the LSM must be capable of displaying the blood pressures as they are measured and storing all blood pressure measurements as required. The storage capacity must be able to handle either 100 readings or 24 hours of data. The stored data must be retrievable upon command and reproduced in a hard copy fashion. The 24-hour storage capability is essential for tracking rhythm changes during sleep. The trend information can be used to compare pressure effects due to zero gravity and as an aid in regulating dosages or assessing the effects of medication.

#### 2.1.4 Automatic Operation

The blood pressure instrument used in the Life Support Module will be reliable and easy to use. Automatic features will help insure reliability and minimize operating requirements. Two automated features are common in blood pressure kits. The digital display frees the user from reading a manometer gauge and the microphone inserted in the cuff frees the user from listening with a stethoscope. Another automatic feature required for the LSM is a cuff inflation source as part of the blood pressure unit. A cuff pump will free the user

from inflating and deflating the cuff with a hand bulb. The pump must meet preset standards. It must inflate the cuff within 12 seconds and the control system must deflate the cuff in steps of 2 to 3 mmHg per second or 2 to 3 mmHg per heartbeat. The pump should not inflate or deflate the cuff at rates that cause pain due to ischemia.

Programmability of the blood pressure unit would free the patient and/or the observer for other duties. The programmability could be as simple as pre-setting a sample cycling time of 6 to 60 minutes. More elaborate programmability would enable the user to set different cycling times throughout a 24-hour period. The manual controls must always have first priority in the operating order for safety reasons.

The automatic features required for the blood pressure unit include digital displays for displaying pressures, the microphone as an integral part of the cuff for reading pressures, and a pump for regulating the inflation and deflation of the cuff. Programmability is also useful for minimizing operating requirements.

#### 2.1.5 Portability

Portability of the blood pressure unit requires a small package that is lightweight. The blood pressure unit chosen for the LSM must be portable enough to be strapped to the user for a long period of time both in earth gravity and zero gravity. During these extended studies the blood pressure unit will be small enough not to hinder the user in performing other duties and will be comfortable to wear. These two features become especially important in the packaging of the blood pressure unit in the space station and in the experiments which are run for extended studies. The blood pressure unit should be small and compact for storage. The weight of the unit is important, especially for the comfort of the subject, when testing is performed on earth.

### 2.2 Equipment Selection

All blood pressure instruments considered for the Life Support Module were commercially available. The previously mentioned criteria were applied to all units. Three blood pressure instruments were chosen for

final evaluation and were brought in house for extensive testing. The units evaluated with full test protocols were:

1. Vita-Stat Model No. 9000-S
2. Critikon Dinamap No. 825
3. ICR Model 5200 Ambulatory Blood Pressure System

#### 2.2.1 Vita Stat Model 9000-S

The Vita-Stat Model 9000-S uses both the auscultatory and the oscillometric methods of measuring pressures. The unit always starts the test in the auscultatory mode, but automatically converts to the oscillometric mode when the microphone is inoperative or no Korotkoff sounds are detected. The average time for a measurement is 28 seconds. If the measurement is not completed within 60 seconds, the pressure in the cuff is released and an error code is displayed. The Vita-Stat 9000-S is specified for a measurement range of 40 to 280mmHg.

The four displays are heart rate, systolic pressure, diastolic pressure, and mean pressure. Indicator lights signal that a rate limit has been exceeded, the oscillometric mode is being used, or that the microphone is improperly placed. Switches on the front panel activate which operational mode (standby, cycling as preset, or manual control) is used.

The Vita-Stat 9000-S has several safety features. The cancel switch causes a measurement in progress to be aborted and the cuff pressure to be released. If any type of error is detected, the pressure in the cuff is automatically released and the appropriate indicator is lit. When the cuff pressure exceeds 300mmHg, it is viewed as an error and the cuff pressure is released.

The Vita-Stat 9000-S can be programmed for a constant cycling time. The programming is achieved through switch settings on the front panel. The cycling time interval is from a minimum of 1 minute to a maximum of 60 minutes. It can be programmed for one cycling rate at a time. The systolic and diastolic alarm limits can be set as desired. The Vita-Stat 9000-S stores the last five blood pressure readings when this mode is appropriately activated by

front panel switches. The systolic and diastolic pressures will be displayed along with a number identifying which of the last five readings is being displayed.

The Vita-Stat 9000-S weighs 11 pounds and measures 14" x 5.75" x 10". This instrument meets all of the criteria of the Statement of Work. Actual readings were taken and are shown in the test results section.

#### 2.2.2 Critikon Dinamap No. 845 XT

The Critikon Dinamap No. 845 XT uses the oscillometric method for blood pressure measurements. The average time for a pressure measurement is 30 seconds; however, this can vary with heart rate and blood pressure. The cuff pressure is automatically released if pressure exceeds 275 mmHg or if AC power fails. The cuff inflation period is 2 to 6 seconds, depending on the size of the cuff. The measurement range for the Critikon Dinamap 845 XT is from 0 to 240 mmHg.

The LED displays show the mean arterial pressure, the systolic pressure, the diastolic pressure, and the heart rate. Indicator lights show which pressure scale is in use (kilo Pascals or millimeters of mercury) and which alarms are on. A flashing LED indicates that an alarm setting has been exceeded. The front panel switches set the 845 XT into a manual control mode, an automatic cycling mode or a hold or a cancel mode. The cycle time switches allow the user to set a desired cycling time.

The safety features include a switch that cancels the measurement taking place, which releases the pressure in the cuff. If the cuff pressure exceeds 275 mmHg or the AC power fails, the cuff pressure is released. A red LED indicates when the alarms have been turned off. A flashing LED indicates that the alarm limits have been exceeded.

The operating cycle of the Critikon Dinamap 845 XT is adjustable from 1 minute to a maximum of 160 minutes. The cycling time steps can be from 1 minute to 16 minutes or it can occur with a X10 factor from 10 minutes to 160 minutes. Only one cycling period can be set at any time. The alarm limits can only be specified for the mean arterial pressure. The alarm is preset at power

turn ON for 140 mmHg high and 50mmHg low. The limits can be reset by a front panel switch in 5 mmHg increments between 20mmHg and 120mmHg for the low limit. The pressures read by the Critikon Dinamap 845 XT are not stored. The pressures are displayed as they are taken. An accessory printer/recorder can be connected through the rear panel. The four outputs of mean arterial pressure, systolic pressure, diastolic pressure, and heart rate are printed.

The 16.5 pound unit measures 4.75" x 11.25" x 11.25". It is line powered and automatically releases cuff pressure when AC power fails. The 845 XT is portable, but it cannot be strapped to the body for extended wear periods. The standard air hose is 12 feet long with an option for a 24 foot dual hose.

The Critikon Dinamap 845 XT meets the established criteria except for data storage capabilities. The unit was further evaluated and the outcome can be seen in the Test Results Section.

#### 2.2.3 ICR Model 5200 Ambulatory Blood Pressure System

The ICR model 5200 ambulatory blood pressure system uses both the auscultatory and the oscillometric methods of measuring blood pressure. The unit always starts the test in the auscultatory mode, but switches to the oscillometric mode when no Korotkoff sounds are detected or if the microphone is inoperative. When the model 5200 monitor has switched to the oscillometric mode, the measured systolic and mean pressure values are used to compute the diastolic value. If the measurement is not completed within 90 seconds, the cuff pressure is automatically released and an error code is shown on the display.

The liquid crystal displays (LCD) on the front of the ICR ambulatory monitor display one parameter at a time. The first numeric quantity supplied is the systolic pressure. The diastolic pressure is the next measurement displayed. The heart rate is the third value. The sequence is repeated twice and cannot be recalled without connecting the RAM pack to the portable operating station. The display also provides a 5-second countdown immediately preceding a measurement. Error codes, if applicable, are also displayed.

When the ON/OFF switch is in the ON position, the START/STOP switch can be used to manually begin a measurement cycle. Both switches can be used during any measuring cycle to terminate the cycle.

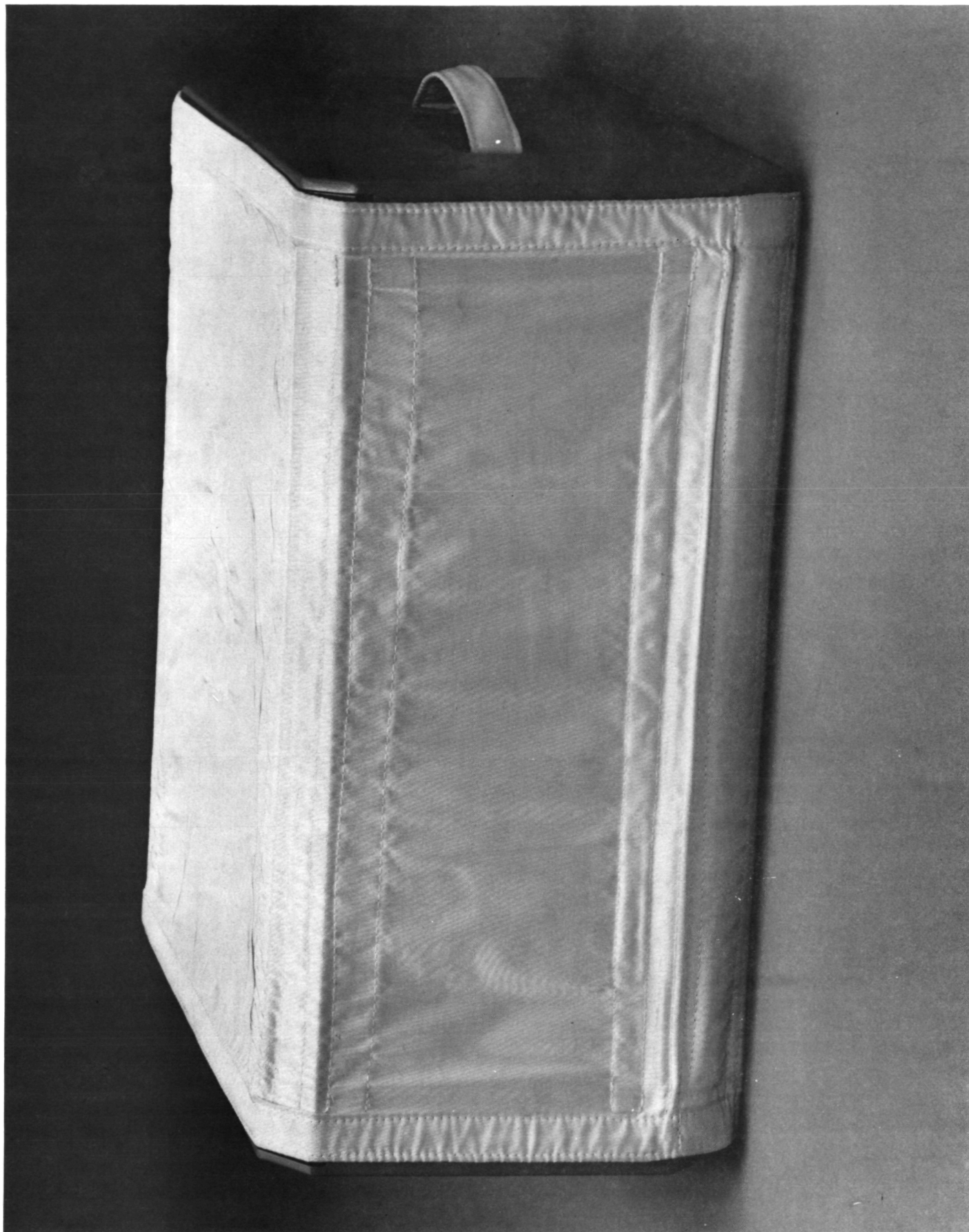
The ICR Model 5200 ambulatory monitor has many safety features. The highest pressure that the pump can achieve is 300 mmHg. Each blood pressure measurement must be completed within 90 seconds. If the 90-second timer runs out, the pressure in the cuff is immediately dumped and an error code is shown on the LCD display. A new measurement cannot begin until 60 seconds has passed and the error code is erased from the display. The six error codes define the following conditions:

1. Blood pressure could not be detected in either the auscultatory or oscillometric mode.
2. Excessive noise or movement.
3. Possible air leak, improper cuff placement, etc.
4. Measurement cancelled by patient.
5. Measurement not completed within 90 seconds.
6. Low battery.

The patient is alerted that an error has occurred by an audible alarm and the error code is displayed. The audible alarm also sounds prior to a measurement cycle so that the patient can avoid motion artifacts. Each time the monitor is turned on, a few seconds are required to perform self diagnostics. When 000 is displayed, the unit is ready for use.

The cycling time for the ambulatory monitor can be set to a single or a multiple cycle time. When the single cycling time is selected, the blood pressure measurement is taken over a 24-hour period at the specified interval. The interval can be selected between 6 and 60 minutes. When the multiple cycling time is selected, the interval can be set differently in each 6-hour time span. The first 6-hour period begins at midnight and the last 6-hour period ends at 11:59 pm. The interval for each period can be set for 6 to 60 minutes. The manual switches always override the programmed cycles, if necessary.

The systolic, diastolic, and heart rate values

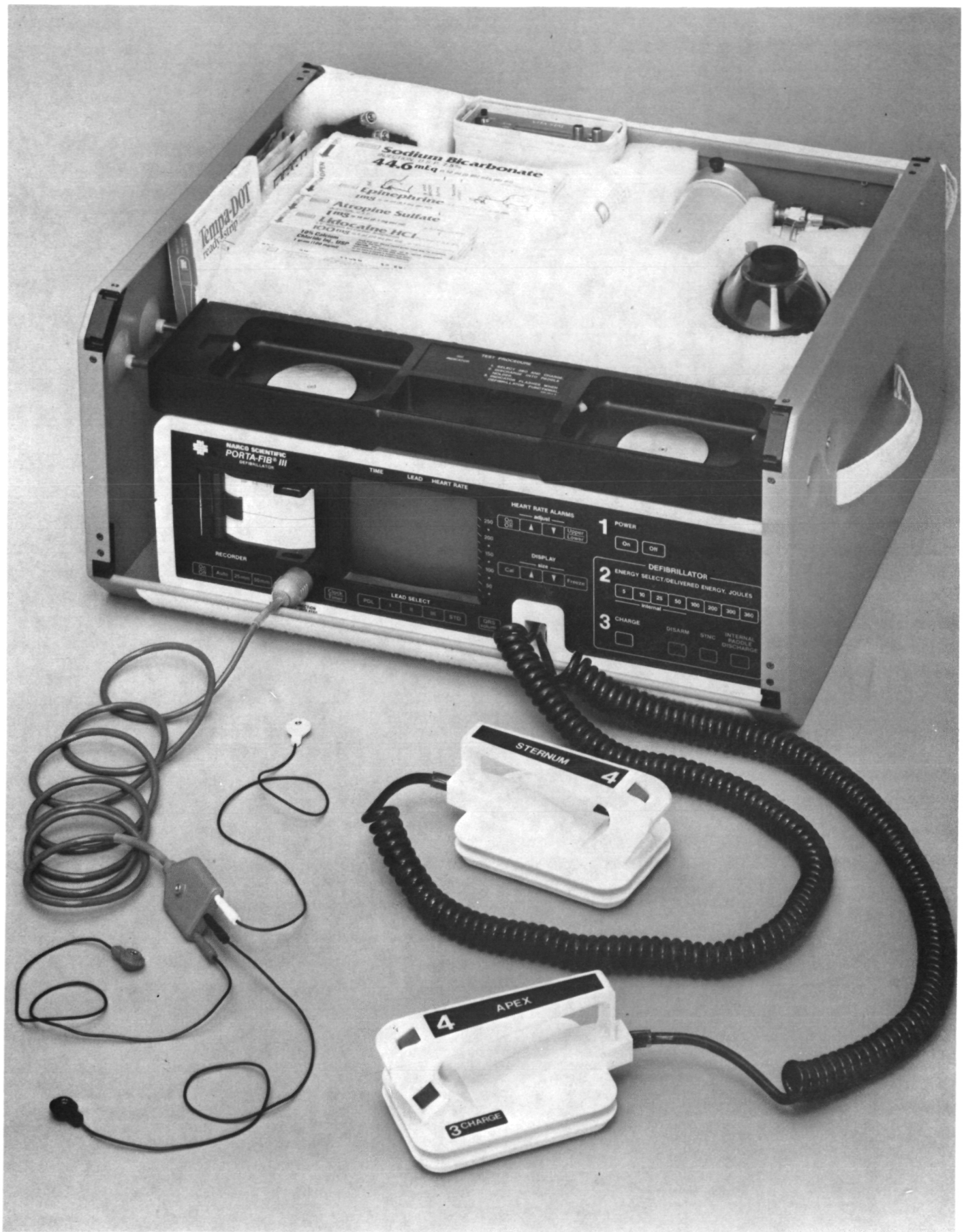


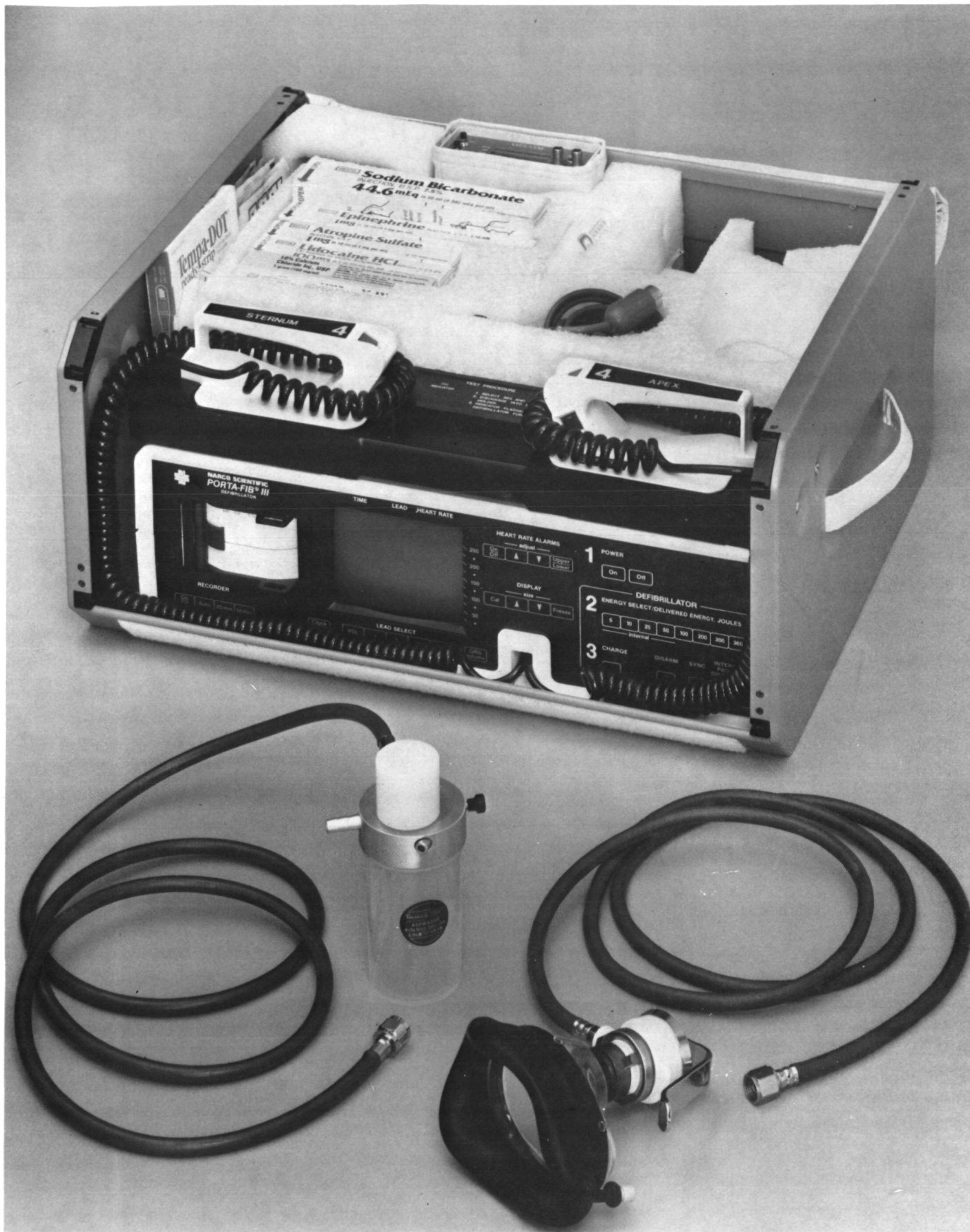






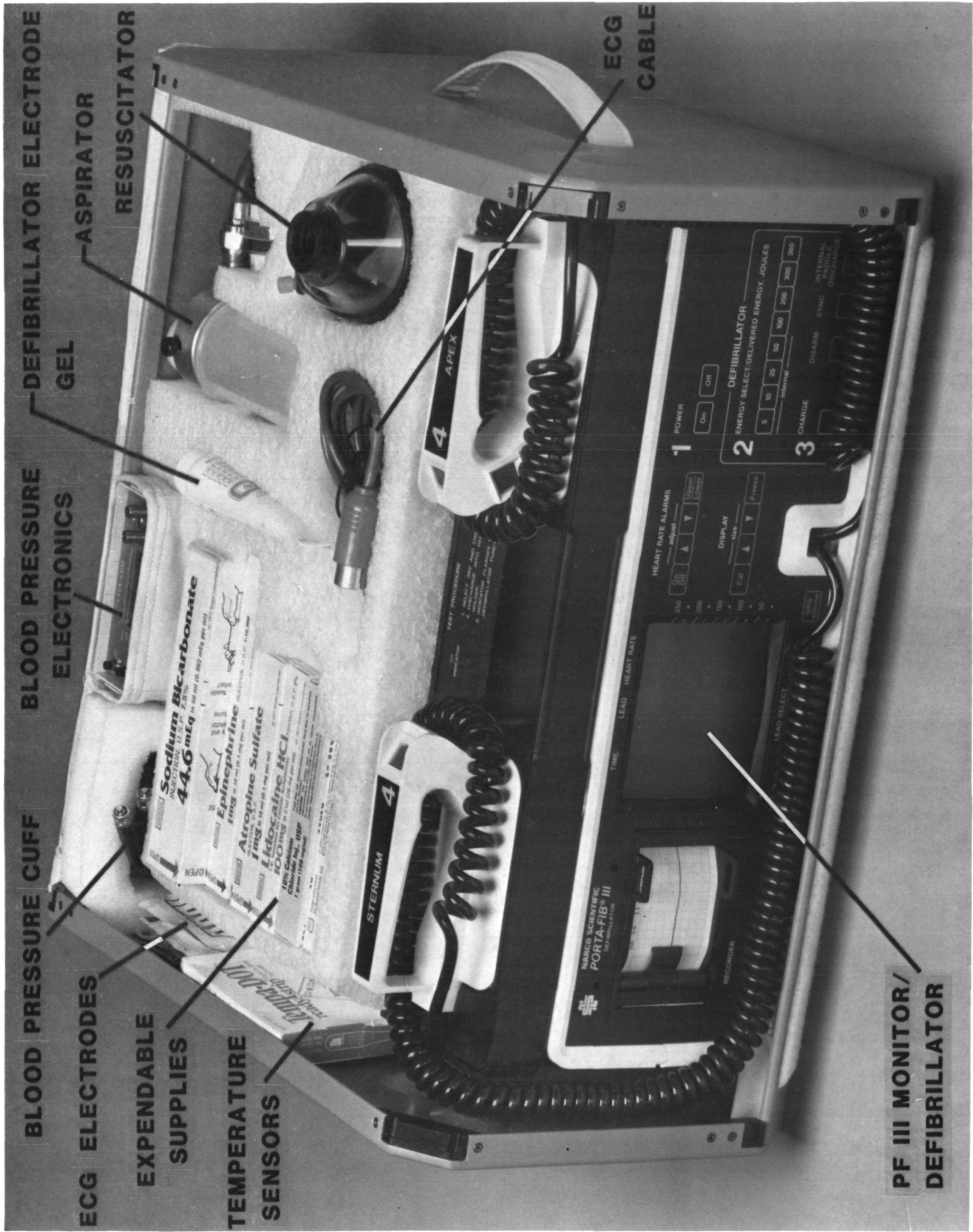












BLOOD PRESSURE CUFF

BLOOD PRESSURE ELECTRONICS

DEFIBRILLATOR ELECTRODE GEL

DEFIBRILLATOR ELECTRODE

EXPENDABLE SUPPLIES

TEMPERATURE SENSORS

ASPIRATOR

RESUSCITATOR

STERNUM

DEFIBRILLATOR

ECG CABLE

PF III MONITOR/DEFIBRILLATOR

are shown on the LCD display after each measurement. These quantities are then stored in the RAM pack. If it is desired to review the measured pressures, the RAM pack is removed from the back of the ICR Model 5200 and inserted into the ICR Model 5300 Portable Operating Station. The blood pressure measurements may then be recorded onto a microcassette tape. These values can be provided on the LCD display of the portable operating station. A hard copy, printed on thermal paper, can also be obtained. The hard copy has several different formats. All data can be listed and the average of all data can be listed. The plot of all data and the plot of the averaged data can be printed.

The ICR Model 5200 ambulatory monitor's dimensions are 8.60"L x 4.75"W x 1.95"D. The monitor with it's vinyl bag and six "C" size batteries weighs 3 lbs. 9 oz. The portable unit can be comfortably strapped to the body and worn for extended periods of time.

The ICR Model 5200 ambulatory monitor meets all of the criteria as specified for an LSM application. Actual test readings are shown in the test results section.

### 3.0 ENVIRONMENTAL SPECIFICATIONS

#### 3.1 Temperature

3.1.1 Storage Temperature, with batteries removed from the Monitor-Defibrillator and Blood Pressure System, should be constrained to 0° to 150° F.

3.1.2 Operating Temperature should be limited to the range of 32° to 100° F.

#### 3.2 Humidity

Relative humidity should not exceed 95% for the Monitor-Defibrillator or Blood Pressure System. The remaining components of the LSM are unaffected by humidity.

#### 3.3 Pressure

Ambient pressure should be constrained within the range of 400mmHg to 800mmHg.

## 4.0 PACKAGING

### 4.1 Materials Listing

#### 4.1.1 Cloth Cover - Beta

PF III

Upper & Lower Case	-	KJB ABS
DFB Paddle Body	-	KJB ABS
DFB Paddle Switch Buttons	-	Nylon
DFB Paddle Cables	-	Polyurethane
Front Panel	-	Polycarbonate
		KJB ABS
Handle	-	KJB ABS
Patient Cable	-	ABS
Patient Cable Adapters	-	Hytrek PVC

#### 4.1.2 Blood Pressure Measurement System

Front Panel	-	Polycarbonate
Soft Case	-	Vinyl
Blood Pressure Cuff		
Hose	-	Buna N
Bladder	-	Buna N
Bladder Cover	-	Polyester
Velcro	-	Polycarbonate

#### 4.1.3 Aspirator

Hose	-	Rubber
Reservoir	-	Polycarbonate
Regulator	-	Nylon

#### 4.1.4 Elder Demand Valve

Hose	-	Rubber
Demand Valve Body	-	Noryl
Face Mask	-	Rubber

### 4.2 Weight Tabulation

Respirator Valve & Hose	0.69 lb.
Respirator Mask	0.16 lb.
Patient Cable & Leads	0.28 lb.
Defibrillator Gel	0.22 lb.
Temperature Strips	0.16 lb.
Aspirator & Regulator	1.00 lb.
Aspirator Suction Catheter	0.06 lb.
ECG Electrodes	0.09 lb.
Blood Pressure Monitor	4.00 lb.
Blood Pressure Cuff	0.69 lb.
Sodium Bicarbonate (50ml)	0.34 lb.
Epinephrine (1mg in 10ml)	0.12 lb.

Calcium Chloride (1 gram in 10ml)	0.12 lb.
Atropine (1mg in 10ml)	0.12 lb.
Lidocaine (100mg in 5ml)	0.12 lb.
Isoproterenol (1mg in 5ml)	0.10 lb.
Chart Paper, 3 rolls	0.60 lb.
Removable Packing Material	0.50 lb.
DFB Paddles, Coil Cables & Connector	2.20 lb.
Paddle Storage & Passive Tester	1.94 lb.
PF III W/O Line Cord	20.20 lb.
10', Low Leakage Line Cord	<u>0.80 lb.</u>

34.51 lb.

0.090 Al Case W/Cover	<u>12.0 lb.</u>
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Total Package Weight	46.51 lb.
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#### 4.3 Power Dissipation Considerations Under Conditions of Zero-G Operation

Measured power input to the PF III at 120 volts, 60 Hz is as follows:

Standby, battery charging only	16.1 watts
Monitor "ON"	29.6 watts
Maximum - Depleted battery & charging DFB, Recorder ON	300 watts

For standby operation, the 16.1 watts is apportioned as follows:

Battery dissipation	3.1 watts
Charge Control Card	3.6 watts
Rear Panel mounted components	0.3 watts
OFF-line switcher	9.1 watts

With Monitor "ON", the dissipation is as follows:

Battery dissipation	3.1 watts
Charge Control Card	3.8 watts
Rear Panel mounted components	3.7 watts
Monitor	8.6 watts
OFF-line switcher	10.4 watts

Power dissipation within the monitor circuitry is estimated as follows:

30% loss in the power supply	2.58 watts
40% loss in the CRT	3.44 watts
30% loss in all electronics	2.58 watts
TOTAL	8.60 watts

The above data do not include dissipation in the defibrillator and chart recorder, both of which are operated with limited duty cycle. The flyback generator



is built around a heatsink which provides a large thermal mass. This system, even when operated under emergency conditions, is noted for cool and reliable performance. The chart recorder circuitry, though dissipating up to 9 watts intermittently, utilizes components which are thermally self-limiting and which are mounted on a heatsink with a reasonable thermal mass. Both of these systems would benefit by the addition of an air-movement device.

At this time, there is no real basis for estimating the proportion of the energy which is carried away by convection. An analysis of the power circuitry shows that all but a few of the components are operated at power dissipation levels of 50% of their maximum power rating or less.

A worst case test could be performed by operating the PF III under near vacuum conditions, but evaluation of the test would require extensive instrumentation and a study program with the assumption that if nothing failed then nothing would ever fail. That is, no visible failure is the same as no degradation of reliability due to operation at elevated temperature. This could be an unjustified conclusion.

The most reasonable approach to the convection problem is the addition of air-moving equipment inside the PF III. Miniature fans are available, powered by either AC or DC, as well as the piezoelectric fans now appearing on the market. The piezoelectric fans feature small size and very low power consumption, but reliability under use conditions common to portable equipment is not known at this time. Brushless, DC-powered fans would move a very large amount of air if any mounting location could be found. This fan, in the absence of Zero-G performance data, would provide a high degree of confidence that reliability would not be degraded.

#### 4.4 Power Interface Considerations

There are three possible power interface options: 115 volts AC, 28 volts DC, and None. The PF III is normally configured to provide power support as follows:

1. Continuous trickle charge to Ni-Cad battery.
2. Augmented battery charge current on demand.
3. Monitor RUN current on demand.
4. Defibrillator power ON demand.

Under low or depleted battery conditions, all of the above power support functions may be required simultaneously. The power requirements, as presently configured and operated on 120 volts AC, ranges from a

low of 16 watts continuous to 300 watts intermittent loading. This dynamic range capability, though appropriate for hospital or clinic applications, might not be required in a shuttle application. As the PF III battery can provide more than three hours of monitoring or 50 full-power defibrillator discharges, on-board power support could be eliminated. This would save several pounds and would eliminate any possible conducted interference, but at the expense of operational flexibility.

The system may be configured to operate from the shuttle DC power, thus eliminating the internal battery and a certain amount of power circuitry. Loading of the 28-volt bus would range from a nominal 0.5 ampere up to a peak of 10 amperes at frequencies through and beyond the audible range. There would be a need for suitable filtering for conducted interference both to and from the PF III. It is not feasible to trickle charge the standard Ni-Cad battery within the PF III using 28-volt DC bus power.

The PF III will function normally when supplied with 115-volt power at 50 through 400 Hz. The standard line-switching inverter is known to produce a nominal amount of conducted interference centered at the operating frequency, 18kHz. This interference increases, in general, as the loading increases. Suitable filtering can be installed to reduce this conducted interference, but it may be very difficult to provide maximum capability without objectionable levels of interference.

The line-switching inverter can easily be replaced with a moderately sized transformer and conventional series-pass regulators provided that defibrillator support is not required.

The most favorable course can be determined after conducted interference is established with various levels of added filtering, and at different loading levels.

#### 4.5 Enclosures

The dimensions of an "experiment storage module" were used as the basis of a rigid container for the LSM which would be interchangeable with existing storage containers. This rigid container was designed to be more rigid than actual flight hardware to ensure that it would be serviceable in the role of prototype equipment. The packaging scheme dictated that the Monitor-Defibrillator was securely mounted to the enclosure shell, as was a modified defibrillator

handle. The handle provided paddle retaining hardware as well as a passive tester for G0/NO-G0 indication of defibrillator function. The remaining volume within the package outline is used for storage of the Blood Pressure Measurement System, Aspirator, Resuscitation equipment, an other accessories such as the ECG cable and electrodes and the drugs and disposable supplies. These items are stored within sculptured styrofoam blocks which are proportioned to fit snugly while allowing easy access to the individual components.

The enclosure is designed to be opened on the top and on one side for access to the Monitor-Defibrillator controls. A fabric cover is secured to the container and provided with Velcro closures. Stainless rods are permanently secured to the fabric cover and the rods align with mating notches at the corners. Two light-duty handles are provided, one at either end. Consideration has been given to providing attachment devices, such as Velcro hooks, to the exterior of the container so that the LSM could be located for convenient use under Zero-G conditions. Of course, the mating Velcro pile would be secured at convenient locations in advance.

## 5.0 TEST RESULTS

### 5.1 Blood Pressure Measuring Device

A test protocol was established to compare the performance of the Critakon Dinamap Model 825 against the performance of the Vita-Stat Model No. 9000-S. Eighty one healthy subjects were evaluated in a double-blind study with simultaneous manual readings taken by a trained observer. A summary of the test conditions and a statistical analysis of the test data follows as Section 5.1.1. The raw data are included in the Appendix.

The conclusion was reached that the instruments both performed adequately. If, however, the performance of the Model 5200 Vita-Stat was equivalent to the performance of the Model 9000-S Vita-Stat, then the size advantages of the smaller Vita-Stat would support the Vita-Stat choice. It was noted further that the secondary features of the Vita-Stat, such as digital storage of the data, were a unique advantage for the LSM application.

Consequently, further study was undertaken to evaluate the Vita-Stat Ambulatory Monitor, Model 5200, in order to demonstrate that the function of the miniaturized ambulatory equipment was equivalent to the larger, stationary blood pressure measurement system. The data

are summarized in paragraph 5.1.2. The conclusion was reached that the performance of the ambulatory monitor was equivalent to the performance of the larger blood pressure system. The reduced data are also included in the Appendix.

### 5.1.1 Summary of Comparison of Indirect Blood Pressure Measurement

Conditions: Resting blood pressures, ambulatory subjects, double-blind readings

#### Equipment Used:

1. Stethoscope & Calibrated Aneroid Gage
2. Critikon Dinamap Model No. 825
3. Vita-Stat Model No. 9000-S

Total Subjects: 81, Approximately 50% Males

#### Pressure Range Encountered:

Systolic - 95 to 180 mmHg  
Diastolic - 60 to 110 mmHg

#### Accuracy Comparison:

##### Pressures in Millimeters of Mercury

<u>Mean Difference (Automatic - Manual)</u>	<u>Systolic</u>	<u>Diastolic</u>
Critikon	5.4	0.2
Vita-Stat	2.0	0.4
<u>Standard Deviation of Differences</u>		
Critikon	4.9	5.0
Vita-Stat	5.2	5.5

### 5.1.2 Summary of Indirect Blood Pressure Measurement using Vita-Stat Ambulatory Monitor

#### Conditions:

Resting Blood Pressures  
Ambulatory Subjects  
Double Blind Readings

#### Equipment Used:

Stethoscope & Calibrated Aneroid Gage  
Vita-Stat Ambulatory Monitor, Model 5200

#### Total Subjects:

20, 50% Males

#### Pressure Range Encountered:

Systolic - 94 - 148 mmHg  
Diastolic - 60 - 92 mmHg

#### Accuracy Comparison:

##### Pressures in Millimeters of Mercury

	<u>SYSTOLIC</u>	<u>DIASTOLIC</u>
Mean Difference (Automatic - Manual)	-3.7	-2.0
Standard Deviation of Differences	4.3	3.0

## 5.2 Aspirator

The standard Robertshaw Controls Co. Aspirator, Model 4213 modified to include a suction pressure regulator, was tested at various flow suction pressures and flow rates using the test equipment described and configured in Figure 7-1. Reduced data are included as Table 7-3, and the results are plotted in Figure 7-2. The test data indicate that the performance meets the design expectations and requirements.

## 5.3 Arrhythmia Detector

The Arrhythmia Detection circuitry was based on an Algorithm described in the literature<sup>1</sup> which is based on a comparison of the most recent R-R interval against the most recent average, or "learned," R-R interval. If this comparison falls outside of specified bounds, the assumption is made that an arrhythmia has been detected. Testing of this circuitry is difficult, as the timing deviations described must be translated into apparent physiological data to facilitate QRS detection.

While it is possible to test using real physiological data, the uncertainties involved make this approach impractical. Consequently, evaluation of the function of the Arrhythmia Detector was based on waveforms generated by a commercial physiological generator, the BIO-TEK Model AS-1 Arrhythmia/ECG Simulator. The results are as follows:

1. From a normal rhythm at 60 beats per minute, the arrhythmia circuitry correctly recognized a waveform and/or rhythm change to: 30 BPM Bradycardia, 120 BPM Tachycardia, Asystole, Pacing, Bigeminy, Heart Block, Arterial Fibrillation, Ventricular Fibrillation, and Ventricular Tachycardia.
2. From a normal rhythm at 60 beats per minute, the arrhythmia circuitry correctly recognized single events as follows: R on T, Fusion Beat, RUN, Missed Beat, Coupled Beat, and Multifocal Beat.

This performance demonstrated that the design objectives had been met.

<sup>1</sup>Sahakian, A.V. et al., "A microprocessor-base arrhythmia monitor/recorder for the operating and recovery rooms." Medical Instrumentation. Vol. 17, No. 2:131-134.

## 6.0 EVALUATIONS AND RECOMMENDATIONS

One complete LSM prototype was submitted to the NASA for evaluation at the conclusion of the initial contract period. It was agreed that the demonstrated performance satisfied the design goals and objectives.

Recommendations were offered relating to the possibility of reducing the weight and volume of the electronic circuitry still further, while at the same time expanding the capabilities. The following specific recommendations should be noted for future systems of this type:

1. Provide an algorithm, within the arrhythmia detector subsystem, that would identify Ventricular Fibrillation and confirm it with a blood pressure measurement.
2. Provide a means of implementing an automatic defibrillation mode.
3. Explore technical and economic feasibility of small flat-screen displays or small, low-power cathode ray tubes.
4. Explore thermilinear array recording techniques that do not rely on the use of a moving, heated stylus.
5. Explore the use of self-contained, battery power which is independent of spacecraft power.

## 7.0 APPENDICES

### 7.1 Theory of Operation - Arrhythmia Detector

The purpose of the Arrhythmia Detector (AD) is to detect timing irregularities in the R-R interval, count these timing irregularity events over a moving time base, and flag an alarm if the count exceeds a predetermined number.

For purposes of this AD system, a timing irregularity is defined as an R-R interval shorter than 75% of the most recent average or longer than 185% of the most recent average.

Please refer to schematic C001-4420 and B231-3780 included in the Service Manual.

When the monitor detects a QRS event there is a negative transition brought in through J1pin4. This pulse is differentiated and inverted through Z1C and Z1. The pulse is used to RESET counter Z2 and gates the ABNORMAL comparator Z8D. Adjustable oscillator



comprised of Z1A, Z1B, and associated components provides a pulse source for counter Z2. The 8 bit output of the Z2 counter is input to the D to A converter Z4 which, together with AR1A, produces a linear voltage ramp which is reset with each QRS event. This ramp function is integrated through R9 onto C8 to produce an analog voltage proportional to the average R-R interval with emphasis on the most recent R-R interval. This voltage is amplified by non-inverting amplifier AR1B by a factor of 3.7 as determined by resistors R10 and R11. As the voltage on C8, proportional to the R-R intervals, is actually equal to one-half of the peak average of the R-R ramps, then the output of AR1B is equal to 3.7 divided by two times the peak average of the R-R ramps. This is used to define the 185% limit. The resistive divider comprised of R12 and R13 is used to establish the 75% limit.

These two voltage levels, 75% and 185% of the voltage representing the average R-R interval, are presented as an input to the comparators AR2 and AR3. Further, the voltage representing the time since the last QRS, generate by AR1A, is also presented to each comparator. The comparator outputs are open-collected and are paralleled to a single pull-up resistor. The inputs to the comparators are such that one comparator output will be ON for all ramp voltages corresponding to R-R times less than 75% of the average R-R interval. This comparator turns OFF for all ramps longer than 75%. The other comparator is connected such that the comparator is OFF until the ramp exceeds a time of 185% of the average, and at that time the comparator turns ON. Thus, there will be a logic low at the input to Z8D before 75% and after 185% (if possible) of the average R-R time when the next QRS is detected, Z8D is gated by the negative pulse from Z1D. If the R-R time is within the 75-185% limits, there will be no output from Z8D. If there is an output from Z8D, this is labelled "ABNORMAL" and sets the R-S flip-flop comprised of Z8B and Z8C. The trailing edge of this "ABNORMAL" pulse is differentiated and, through Z7A, clocks the UP-DOWN counter Z5. Setting the R-S flip-flop, as described above, sets the UP-DOWN input to the counter to count UP. The CLOCK input to the counter is also connected to RESET the R-S flip-flop and thus changes the input to count DOWN. A second adjustable oscillator is driving a multi-stage counter, Z3, whose output is gated into the CLOCK input of the UP-DOWN counter Z5. As the R-S flip-flop described above normally controls the mode input to the UP-DOWN counter to be "DOWN," the counter subtracts one count from the UP-DOWN counter each time Z3 cycles through. This provides a steady subtraction of ABNORMAL events, such that only an ABNORMAL rate higher than pre-determined will flag an alarm. The

subtraction gating function simply precludes subtracting past zero, as gate Z7B is disabled when the counter output equals zero. The subtraction rate is adjusted by changing the frequency of the oscillator driving Z3. The output of the UP-DOWN counter is fed into a one-of-ten decoder, Z6, where the binary input is converted to a single LOW output corresponding to the input binary code. An array of ten light-emitting diodes is connected to provide a visual display of the counter state at any time. The decoder outputs are individually connected through an eight pole DIP switch to a single pull-up resistor which is also connected to J1-3. The DIP switch allows programming of the number of ABNORMAL events required to flag an ABNORMAL condition.

The count function of the AD is defeated unless the operator selects active alarms for heart rate limits. When active alarms are selected, a high level is present at J1-6 which is inverted through Z8A and presented to the RESET function of the UP-DOWN counter Z5. This releases the RESET function. Cancelling the alarms serves to reset the UP-DOWN counter to zero, which is a convenient method of cancelling inputs due to artifacts which would otherwise maintain an alarm for an inconvenient period.

## 7.2 Detailed Operating Instructions, Arrhythmia Detector

Arrhythmia Detector Instructions are broken down to the following categories as follows:

Initial Adjustment - Initial Adjustment is limited to setting the minimum heart rate. The ramp developed at TP4 must not over-range and fold back at the longest R-R period to be considered. The frequency of the oscillator comprised of Gates Z1A and Z1B and associated components is adjusted through R3. At 40 beats per minute, the frequency at pin 5 of Z2 is 5.6 milliseconds. Other minimums may be established if desired. If a longer R-R period is encountered, such as following a PVC, and the ramp does reset, this event will still be recognized as an abnormal timing event while the ramp is still in the 0 to 75% timing region. This, in effect, extends the lower range for occasional events.

Definition of Arrhythmia Limits - Definition of Arrhythmia Limits includes establishing the moving time base and the number of arrhythmias counted during this time window required to set the arrhythmia flag. Setting the moving time base can be interpreted as the "subtraction rate" of the "DOWN" inputs to the UP-DOWN

counter Z5. The oscillator driving counter Z3 controls the subtraction rate. A period of 7.0msec at TP2 produces one subtraction every 30 seconds. The subtraction period, which can be measured at TP3, is directly proportional to the period at TP2. The state of the arrhythmia counter is displayed by the array of LED's DSO through DS9. The counter contents equals ZERO when DSO is illuminated and holds a count equal to the LED number. Selection of the arrhythmia flag limits requires turning ON the DIP switches provided in S1. It is not possible to select an arrhythmia count of ONE. Switch number one is connected to the output corresponding to an arrhythmia count of two, and all of the S1 switches (eight individual switches within the S1 package) are assigned in like manner. The eighth switch selects an arrhythmia count to nine. In selecting the alarm count, the proper S1 switch must be pressed down on the side marked ON. Further, all S1 switches higher than the selected switch must also be turned ON. If this is not done, the arrhythmia detector will flag that the limit has been reached when the count is the exact value only, ignoring the condition when the count number continues to increase.

**System Operation** - The arrhythmia detection circuitry is functioning at all times when the system power is ON. However, the arrhythmia counter is forced to a count of zero at all times unless the heart rate alarms are selected to be active via the HEART RATE ALARMS switch on the front panel. When the alarms are active, the green LED will be illuminated above the Heart Rate Alarms ON/OFF selector switch. When the arrhythmia limit has been reached or exceeded, the Heart Rate Alarm tone will sound, recognizable as an alternating tone. In addition, the alarm condition will be indicate on the CRT as follows:

1. If the alarm condition is a heart rate outside of the set limits, then a letter will appear on the CRT between the indication of selected ECG lead and the indication of present heart rate. This letter will be an "H" for a high heart rate or an "L" for a low heart rate. The alarm indication will persist until manually shut off or the heart rate returns to within the set limits.
2. If the alarm condition is an arrhythmia count out of limits and there is no heart rate alarm, then the alarm tone will sound and the letter "A" will appear as above. The alarm condition indication gives priority to displaying heart rate before arrhythmia. The alarm tone will sound for any out-of-limit condition.

The arrhythmia counter can be rapidly reset to zero by briefly turning the heart rate alarms OFF. This is a convenient procedure to cancel inputs due to artifact or other anomalies.

### 7.3 Experimental Data

#### 7.3.1 Test Data, Comparison of Critikon vs. Vita-Stat Blood Pressure Systems, Table 7-1.

<u>Name</u>	VITA-STAT MEASUREMENT	MANUAL MEASUREMENT
	<u>mmHg</u>	<u>mmHg</u>
J.J./M	103/77	110/74/72
T.L./F	140/80	134/76
M.T./M	140/92	136/92
C.N./F	115/73	109/70
K.T./F	125/85	122/80
N.H./F	118/77	114/74
D.S./M	143/87	142/88
G.M./M	153/70	145/70
F.E./M	135/80	132/78
G.T./M	135/65	130/68
C.B./F	130/92	120/78
T.W./F	113/70	110/68
M.F./M	130/85	133/82
A.H./F	133/62	130/68
J.G./F	103/62	100/62
E.C./F	130/85	128/80
M.S./F	122/80	122/78
J.C./M	108/65	110/65
S.A./M	130/85	128/80
D.W./F	118/77	116/72
C.B./F	105/65	109/62
A.R./F	120/70	118/68
D.S./F	125/77	122/73
S.C./F	95/77	122/78
H.R./F	148/93	145/95
J.G./M	177/80	172/90
J.B./M	118/77	115/76
G.R./M	117/73	112/72
P.S./M	157/75	150/75
B.N./M	187/125	180/103
C.S./M	128/70	126/68
C.C./M	135/92	132/100
S.M./F	115/65	113/68
T.S./M	143/77	136/80
P.M./M	118/73	115/73
M.G./F	135/85	130/85
G.M./M	148/75	140/75
P.N./M	125/80	122/80
B.T./F	107/73	105/75
D.R./F	125/62	124/67
I.C./F	103/73	103/72
M.B./M	153/90	150/87
R.S./M	115/77	117/75
M.C./F	110/73	114/74
K.B./F	122/73	122/75

V.W./F	115/70	115/70
L.T./F	115/73	112/75
I.C./F	100/70	98/78
D.N./M	125/77	122/74
L.A./F	125/77	122/75
S.B./M	122/77	118/75
R.W./F	95/70	98/70
C.B./F	122/85	118/95
B.M./F	135/80	128/80
C.S./M	125/73	124/78
G.M./F	110/65	108/67
H.K./M	120/73	120/72
B.T./M	142/92	138/92
E.B./F	107/70	104/70
J.B./F	107/73	108/70
W.M./F	125/80	125/80
B.D./M	122/50	120/70
B.S./F	125/77	122/75
M.H./F	135/85	130/88
D.S./M	118/70	115/72
A.Q./M	120/80	120/80
L.S./F	133/80	127/80
H.N./F	98/60	118/60
C.M./M	100/80	100/82
B.H./M	125/65	120/67
G.Z./M	125/80	122/78
L.C./F	115/77	115/74
J.R./M	142/77	140/76
L.B./F	115/62	115/65
L.R./M	118/73	116/70
R.M./M	130/85	122/83
S.C./M	122/73	115/68
J.W./F	110/77	110/76
D.R./M	147/85	140/90
A.S./M	143/105	136/92
A.L./M	118/77	122/78

CRITIKON  
MEASUREMENT  
-----  
mmHg

MANUAL  
MEASUREMENT  
-----  
mmHg

C.C./M	136/88	122/92
S.M./F	110/69	108/68
T.S./M	139/73	138/82
P.M./M	119/67	106/68
M.G./F	126/81	125/83
G.M./M	130/84	138/76
P.N./M	137/85	123/82
B.T./F	109/60	105/70
D.R./F	127/80	118/77
T.C./F	108/65	100/70
M.B./M	144/95	146/96
R.S./M	122/71	116/75
M.C./F	115/68	109/78

K.B./F	129/78	120/71
K.W./F	124/73	116/75
K.T./F	113/79	112/77
I.C./F	96/66	95/67
D.N./M	123/73	120/78
L.A./F	123/75	124/82
S.B./M	120/68	113/68
R.W./F	107/76	98/68
C.B./F	123/85	115/86
B.M./F	144/87	136/88
C.S./M	118/73	122/86/79
G.M./F	114/70	107/70
H.K./M	114/70	118/78
B.T./M	143/94	141/98
E.B./F	118/74	112/74
J.B./F	117/73	110/76
W.M./F	137/89	129/90
B.D./M	131/79	123/75
J.J./M	113/77	105/72
T.L./F	134/79	125/78
M.T./M	141/98	135/96
C.N./F	126/79	117/72
K.T./F	124/89	123/82
N.H./F	122/80	115/76
D.S./M	157/87	142/95
G.M./M	148/85	147/82/78
F.E./M	140/80	133/86
G.T./M	136/61	127/67/62
C.B./F	121/95	120/92
T.W./F	133/84	130/80
M.F./M	131/82	123/83
A.H./F	134/79	132/70
J.G./F	110/67	98/65
E.C./F	127/83	128/84
M.S./F	134/85	125/85
J.C./M	120/79	111/72
S.A./M	134/85	132/82
D.W./F	117/73	115/76
C.B./F	117/73	112/67
A.R./F	124/78	128/73
D.S./F	128/75	123/75
S.C./F	130/85	120/84
H.R./F	141/92	138/90
J.G./M	162/95	151/94
J.B./M	107/70	110/80
G.R./M	107/70	110/71
P.S./M	147/81	146/80
B.N./M	174/113	167/110
C.S./M	150/68	142/79
B.S./F	123/75	121/83
M.H./F	129/85	125/85
D.S./M	131/79	122/63
A.Q./M	131/68	117/72
L.S./F	130/77	122/80/74

H.N./F	127/74	119/75
C.M./M	121/74	99/78
B.H./M	124/72	117/77
G.Z./M	126/82	118/82
L.C./F	114/75	110/70
J.R./M	134/79	135/80
L.B./F	119/66	117/68
L.R./M	143/79	125/75
R.M./M	132/88	133/86
S.C./M	128/73	126/72
J.W./F	122/84	112/82
D.R./M	141/93	135/95
A.S./M	134/90	130/97
A.L./M	131/91	123/90

### 7.3.2 Reduced Data Vita-Stat Model 5200

TABLE 7-2

<u>Date</u>	<u>Subject</u>	<u>Observer</u>	<u>Condition</u>	Vita-Stat Reading <u>mmHg</u>	Observer Reading <u>mmHg</u>
11-17-83	GZ	LB	LA-sitting	120/80	122/82
11-17-83	DW	LB	LA-sitting	113/87	118/85
11-17-83	LR	LB	LA-sitting	107/83	106/82
11-17-83	AQ	LB	LA-sitting	101/61	108/68
11-17-83	BS	LB	LA-sitting	141/87	140/90
11-17-83	RM	LB	LA-sitting	121/76	122/82
11-17-83	BT	LB	LA-sitting	133/87	138/92
11-17-83	CM	LB	LA-sitting	95/72	104/76
11-17-83	DS	LB	LA-sitting	140/83	142/84
11-17-83	DS	LB	LA-sitting	140/83	140/92
11-17-83	HN	LB	LA-sitting	142/87	140/88
11-17-83	IH	LB	LA-sitting	90/63	94/66
11-17-83	DS	LB	LA-sitting	116/72	122/76
11-17-83	CB	LB	LA-sitting	118/68	132/70
11-17-83	SC	LB	LA-sitting	113/83	114/82
11-17-83	JW	LB	LA-sitting	113/80	118/80
11-17-83	AR	LB	LA-sitting	106/72	118/70
11-17-83	GT	LB	LA-sitting	146/88	148/88
11-17-83	LC	LB	LA-sitting	120/76	122/75
11-17-83	TC	LB	LA-sitting	113/76	118/76



7.3.3 Test Procedure, Aspirator Flow vs. Suction Pressure Evaluation

7.3.3.1 Interconnect the test apparatus as detailed in Fig. 7-1.

Open the Whitey Valve fully and turn the Aspirator Regulator Control CCW about five turns. This will reduce the risk of overpressuring the sensitive pressure gage.

7.3.3.2 Turn ON the oxygen cylinder valve. Note and record the oxygen cylinder pressure.

7.3.3.3 Close the Whitey Valve.

7.3.3.4 Adjust the aspirator pressure regulator to a zero-flow pressure of approximately ten inches of water. Record the flow volume and regulator pressure at zero flow and at various settings of the Whitey valve up to maximum flow.

7.3.3.5 Close the Whitey valve and readjust the suction pressure to an intermediate suction pressure. Readjust the flow and record data.

7.3.3.6 Continue as in step 5 until the data of interest has been recorded.

7.3.3.7 Note and record the oxygen cylinder pressure.

7.3.3.8 Close the oxygen cylinder valve.

FLOW vs PRESSURE TEST CONFIGURATION

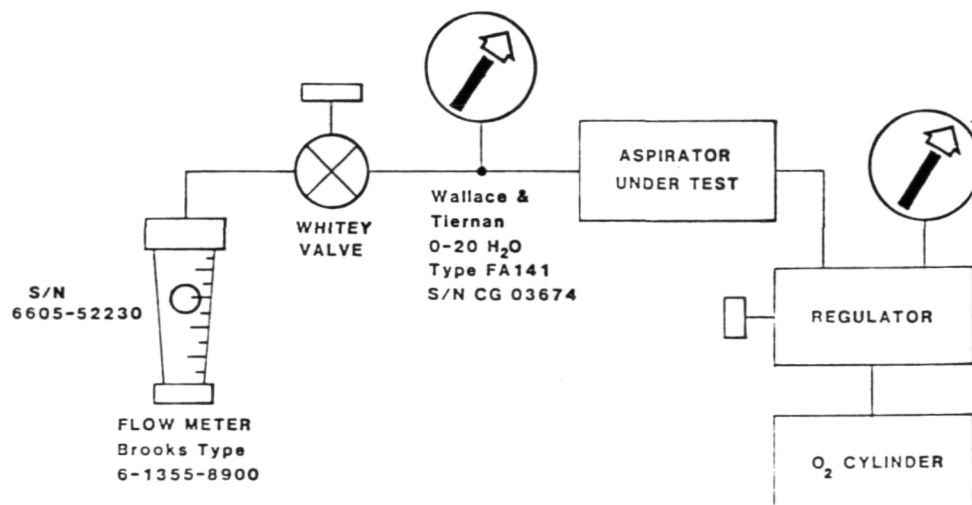


FIGURE 7-1

TABLE 7-3  
REDUCED DATA  
ASPIRATOR FLOW PRESSURE VERSUS ASPIRATOR FLOW VOLUME

Constant Pressure Setting	Air Flow, SCFM = (0.0454) x (% Reading)
Suction Pressure, <u>inches of H2O</u>	Suction Flow <u>SCFM</u>
18.6	0
15.6	0.454
14.3	0.636
10.4	0.908
15.0	0
11.3	0.454
10.1	0.636
9.1	0.908
7.9	0.999
12.0	0
9.1	0.454
7.1	0.726
6.2	0.908
10.0	0
6.6	0.454
5.2	0.726
20	1.0896
15	1.5436

TABLE 7-4  
RAW DATA  
ASPIRATOR FLOW PRESSURE VERSUS ASPIRATOR FLOW VOLUME

Flowmeter - Brooks Type 6-1355-8900

Aspirator Pressure, inches of H2O	Flowmeter Reading, %F.S.	02 Cylinder Pressure, PSIG
15.0	34	1400
20	24	
14.3	14	
15.6	10	
10.4	20	
18.6	0	
15.0	0	
11.3	10	
10.1	14	
9.1	20	
7.9	22	
12.0	0	
9.1	10	1200
7.1	16	
6.2	20	

# ASPIRATOR SUCTION PRESSURE VS FLOW VOLUME, SCFM AIR

G. ZIVLEY, 1984

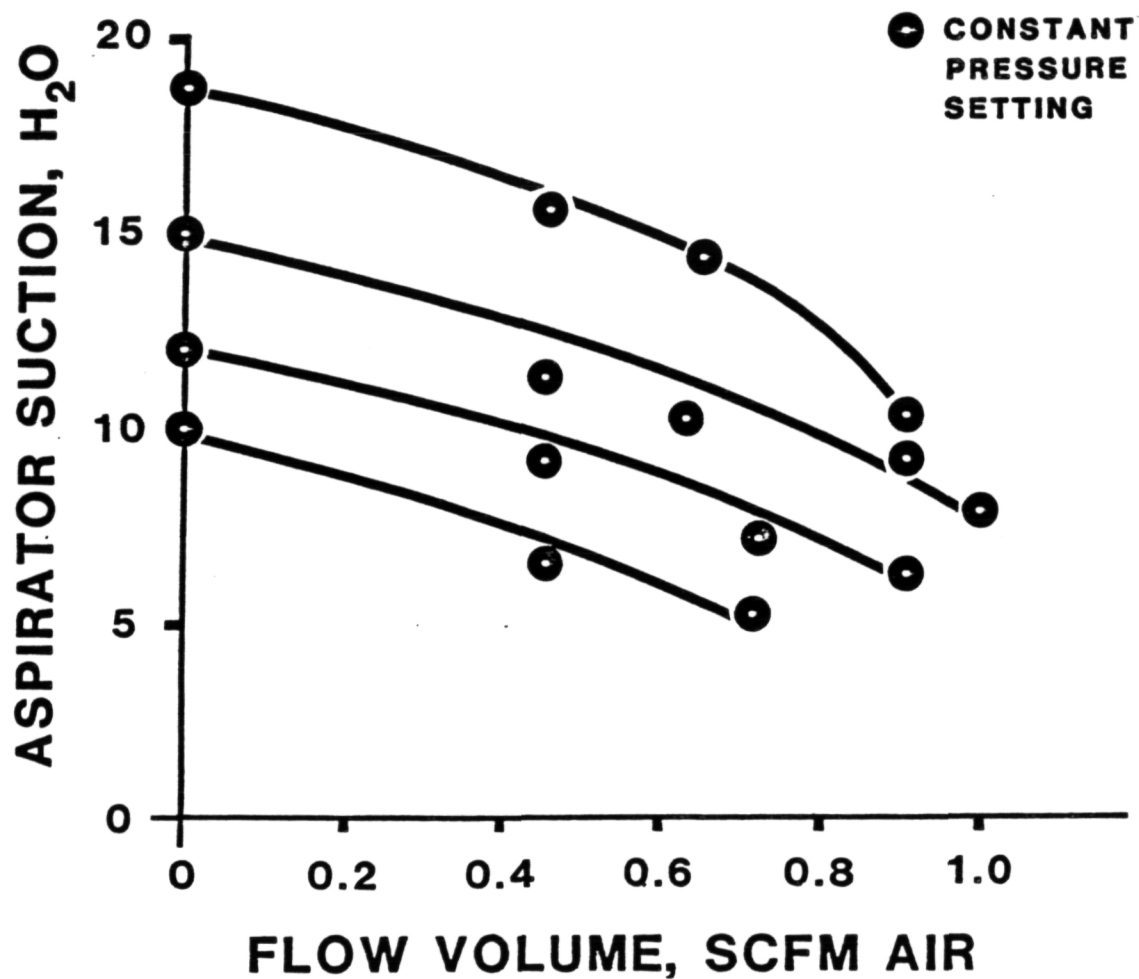


Figure 7-2

#### 7.4 Manufacturers Data Sheets

The ICR 5200 Ambulatory Blood Pressure Monitor is ideally suited for the diagnosis of hypertensive patients, particularly the borderline and labile cases.

Resting blood pressure readings may not give the most accurate evaluation of changes in blood pressure or 24-hour averages.

The Model 5200 provides periodic monitoring of blood pressure and heart rate, round the clock. Three cuff sizes assure proper fit for accurate readings, with no ECG leads. . . for greater patient compliance.

Patients can see the reading right on the monitor—systolic, diastolic, and heart rate. The cuff pressure adjusts itself to the previous systolic pressure reading for patient comfort. Blood pressure readings can also be initiated when patients feel an episode or the need for biofeedback.

- ☐ 24-hour ambulatory blood pressure monitoring: systolic, diastolic, and heart rate
- ☐ Five-second countdown feature lets patient relax before readings
- ☐ Pre-programmed measurement intervals; time intervals adjustable from 6 to 60 minutes, or patient-initiated readings
- ☐ Microprocessor program discriminates between pressure signals and extraneous sound
- ☐ Lightweight (approx. 3½ pounds) for portability
- ☐ Unique cuff design for patient comfort, convenience
- ☐ Five different error codes to aid data review and acquisition
- ☐ Detachable RAM PACK data storage system with all-digital memory
- ☐ Uses disposable batteries; provides accuracy to AAMI specifications

# ICR 5200 Monitor



**Spacelabs**  
A Squibb Company



# ICR 5200 Monitor Specifications

## Controls, Connectors and Indicators

**ON/OFF** — Two position slide switch.

"ON" — Normal operation — allows monitor to cycle on pre-programmed time intervals.

"OFF" — Standby mode, no cycling occurs, data retained.

**START/STOP** — Pushbutton depressed to begin manual blood pressure measurement if none in progress. Overrides present cycle time, and resets timer.

If depressed during blood pressure measurement, unit will abort cycle.

**AUDIO** — Audible tone indicates start of a cycle or an error code has been obtained.

## General

**MEASUREMENT RANGES** — Heart Rate: 40 to 180 bpm; pressure 70 to 270 mmHg for systolic, 40 to 150 mmHg for diastolic, and 50 to 180 mmHg for mean arterial values. Monitor is designed to operate between 40 to 280 mmHg. Clinical tests have verified accuracy in accordance with proposed AAMI standards.

**PRESSURE MEASUREMENT METHOD** — Auscultation method when Korotkoff sounds are audible, with a back-up method of oscillometry when Korotkoff sounds cannot be heard.

**AUTOMATIC MEASUREMENT INTERVALS** — Physician may adjust time interval from six minutes minimum to 60 minutes maximum, by preprogramming RAM PACK. These cycles can be pre-programmed to change during the day and night to more frequent or less frequent time intervals.

**MEASUREMENT CYCLE TIME** — Typically 20-50 seconds; cuff inflated to pressure mmHg for no longer than 90 seconds.

**MAXIMUM CUFF PRESSURE** —  $300 \pm 10$  mmHg

**AUTOZEROING** — Pressure transducer channel automatically zeroed before each reading.

**ARTIFACT REJECTION** — Microprocessor program discriminates between pressure signals and extraneous sounds, such as patient movement.

**CUFF INFLATION/DEFLATION** — Automatic, motor driven pump operation. Deflate rate under microprocessor control.

**DATA STORAGE SYSTEM** — Nonvolatile CMOS 2K RAM, located in battery pack. Information retained until batteries are replaced. Timing of events provided by real time clock in battery pack.

**DIGITAL DISPLAY** — 3 digit, 7 segment, liquid crystal display. Systolic, diastolic, and heart rate information to be alternately displayed. Blinking cursor provided to indicate when unit is on.

**PATIENT SAFETY** — Measurement cycle under 90 second timing control. Pneumatic system open when off. Air harness detachable at cuff. Independent over pressure sensor to interrupt system at 300 mmHg. 510K approval.

## Physical

**POWER REQUIREMENT** — Replaceable battery pack consisting of six C-size, non-rechargeable batteries.

**DIMENSIONS** — 8.60"L x 4.75"W x 1.95"D

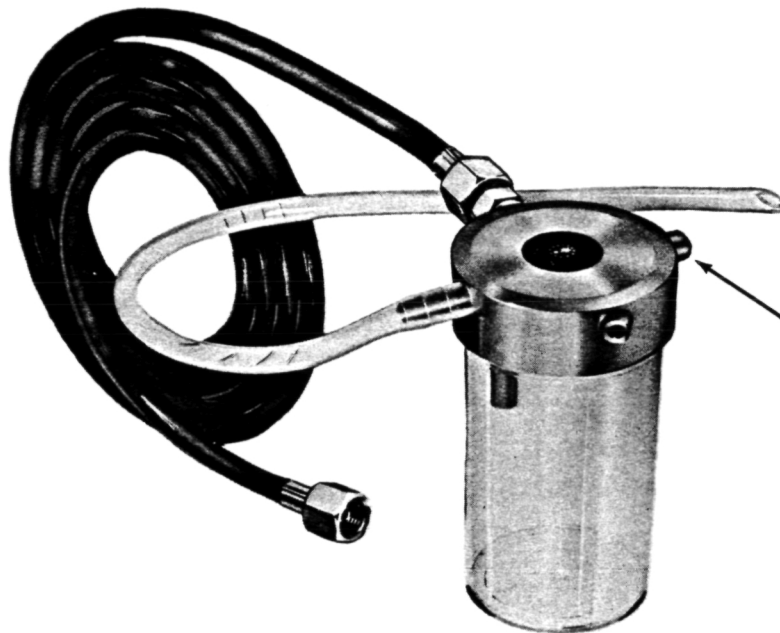
**WEIGHT** — Monitor, vinyl bag and batteries — 3 lbs. 9 oz.



**Spacelabs**

A Squibb Company

Ambulatory Blood Pressure Division  
13208 Northup Way  
P.O. Box 6639  
Bellevue, Washington 98008-0639  
206-641-5410 outside Washington 800-426-2670



## Aspirator

— PRESSURE KNOB

### DESCRIPTION

The Robertshaw Aspirator, Part No. 900-002-146, when used in combination with Robertshaw Portable Resuscitators, provides a fast effective method of clearing fluids/mucus from a patients airway passages in emergency situations. The Robertshaw Aspirator is designed to operate in conjunction with portable oxygen cylinders equipped with a pressure regulator or from a central oxygen source. The oxygen source should provide an inlet pressure of 40 to 90 psig (275-620 kPa).

The Aspirator has both manual and constant flow capabilities. The unit can be operated manually by depressing the pressure knob when suction is needed. If constant flow suction is desired, the button may be depressed and turned clockwise to lock it in place for use with a catheter that features a thumb port to control suction.

A positive pressure can be applied to the Aspirator to remove stubborn mucus plugs or for partial emergency emptying of an overfilled Aspirator Jar, by covering the Aspirator Orifice with a finger. During the positive pressure cycle, oxygen under pressure flows through the Aspirator Jar and out through the tip of the Catheter.

### ASPIRATION

Establish the need for aspiration prior to resuscitative efforts. A minimum amount of time should expire prior to initiating resuscitative efforts. Generally, observation of the patients mouth will indicate the need for aspiration.

1. Connect the hose to an oxygen supply capable of delivering 40 to 90 psig (275-620 kPa) to the Robertshaw Aspirator and

S-L-O-W-L-Y turn ON the oxygen supply. After the initial S-L-O-W opening, the valve should be fully opened.

2. Open the patients mouth and carefully insert the aspirating tip of the Catheter. Use gentle stroking motions - DO NOT JAB.
3. Depress the Aspirator Control Button.
4. Care should be taken not to invert the jar so that fluid will not enter the venturi system.

### PERIODIC TESTING

The Aspirator should be tested periodically to insure proper performance. The frequency of testing should be established according to usage; however, testing should be performed at least once a year. To test the Aspirator, verify that the Aspirator Jar is empty, connect a standard catheter to the Aspirator, then aspirate a sufficient quantity of water into the Aspirator Jar to cause discharge through the Aspirator Orifice. The time required to cause the discharge should not exceed 5 seconds.

### SPECIFICATIONS

**Supply Pressure** - 40 to 90 psig (275-620 kPa)

**Suction Pressure** - 407 mm Hg minimum at 50 psig (345 kPa)

**Flow Suction** - 15 LPM minimum at 50 psig (345 kPa)

**Inlet Fitting** - Standard Diameter Index Safety System, .562 x 18 external thread

**Filters** - 65 micron (1.6 micrometers) sintered bronze (replaceable)

**Finish** - Clear anodized aluminum



### CLEANING PROCEDURE

The aspirating Catheter (2) should be flushed with water as soon as possible after treatment of the patient to remove mucus, vomitus, etc. Should the Aspirator Jar (5) become overfilled causing obstruction of the Aspirator Orifice (3), remove the Aspirator Orifice (3) retained by Setscrew (4) and thoroughly clean. Do not damage O-rings (10) when removing or replacing the Aspirator Orifice (3).

### REPLACEMENT OF FILTER

1. To replace Filter (7), disconnect Hose Assembly (9) and remove Spring (6) and Filter (7) from Fitting (8).
2. Insert new Filter (7) oriented as shown and Spring (6) into Fitting (8). Verify that the large coil of Spring (6) is placed over Filter (7). (See Figure 1).
3. Reconnect Hose Assembly (9) to Fitting (8). It is not necessary to tighten fittings with a wrench.

### DISINFECTING

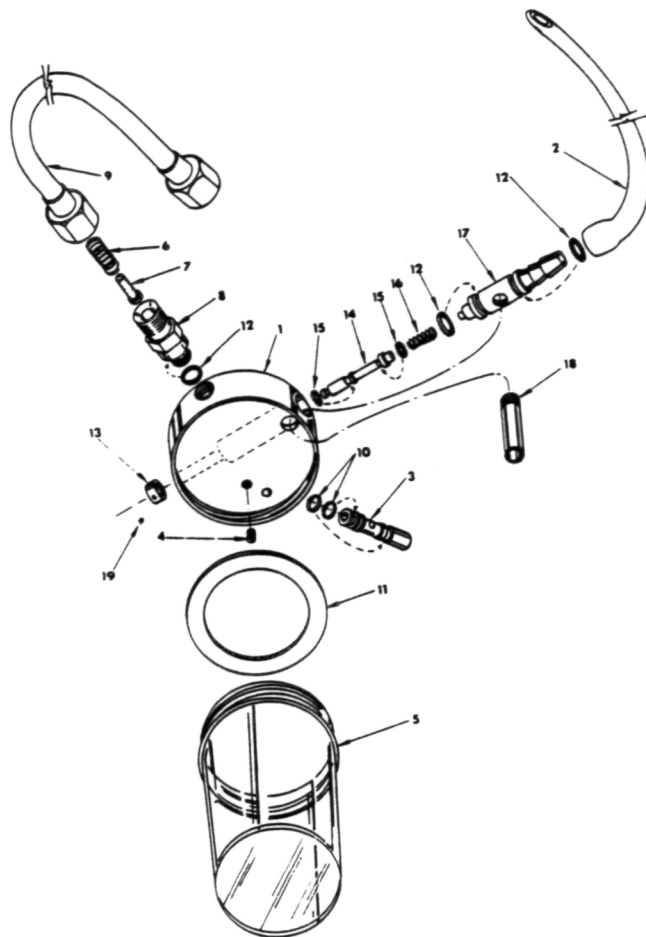
1. Cold Sterilization
  - a. Remove the Hose Assembly (9) and immerse the Body Assembly, Gasket (11), Catheter (2), and Aspirator Jar (5) in a CIDEK solution for a minimum of 10 minutes.
  - b. Remove the Body Assembly, Gasket (11), Catheter (2), and the Aspirator Jar (5) from the CIDEK solution and RINSE THOROUGHLY in sterile water with multiple repeated rinsings.
  - c. Remove the Body Assembly, Gasket (11), Catheter (2), and Aspirator Jar (5) from the sterile water and using sterile technique THOROUGHLY DRY.
  - d. Carefully examine the equipment. Discard any cracked or damaged parts. Replace Filter (7) as necessary.
  - e. Reassemble and return to use.
2. Gas Sterilization

Gas Sterilization techniques (e.g. ethylene oxide) may also be used; however, the sterilizer temperature must not exceed 160°F (344°K). If gas sterilization is used, aeration of the Aspirator must be of sufficient duration to remove all traces of the sterilizing agent.

### WARNING

Disassembly, assembly and testing of the Aspirator should be performed by experienced personnel only. The work area should be free of hydrocarbon residues because of the danger of spontaneous combustion when the residues are exposed to gaseous oxygen. Robertshaw recommends that the Aspirator be returned to the factory for overhaul and/or repair.

**Robertshaw**  
CONTROLS COMPANY  
Life Support Products Marketing Group  
333 N. Euclid Way, Anaheim, CA 92803



### PARTS LIST

1.	904-002-948	Body
2.	904-002-950-24	Catheter
3.	595-900-047	Aspirator Orifice
4.	435-621-353	Setscrew
5.	475-900-016	Aspirator Jar
6.	577-900-108	Spring
7.	520-900-027	Filter
8.	525-900-100	Fitting
9.	535-900-026*	Hose Assembly
10.	560-634-008	O-Ring
11.	560-900-042	Gasket
12.	560-634-011	O-Ring
13.	150-900-052	Button
14.	585-900-056	Poppet
15.	560-625-004	O-Ring
16.	577-900-091	Spring
17.	525-900-125	Stem
18.	525-900-124	Tube
19.	435-620-152	Setscrew

\*The length of standard hose assembly is 6 feet. To order hose assemblies of different lengths specify Part No. 535-900-026-XX (where XX is length in feet). For hose assemblies greater than 15 feet, specify Part No. 535-900-033-XX (where XX is length in feet).

# Elder Demand Valve

MODEL 34

Instruction Sheet

July 1982

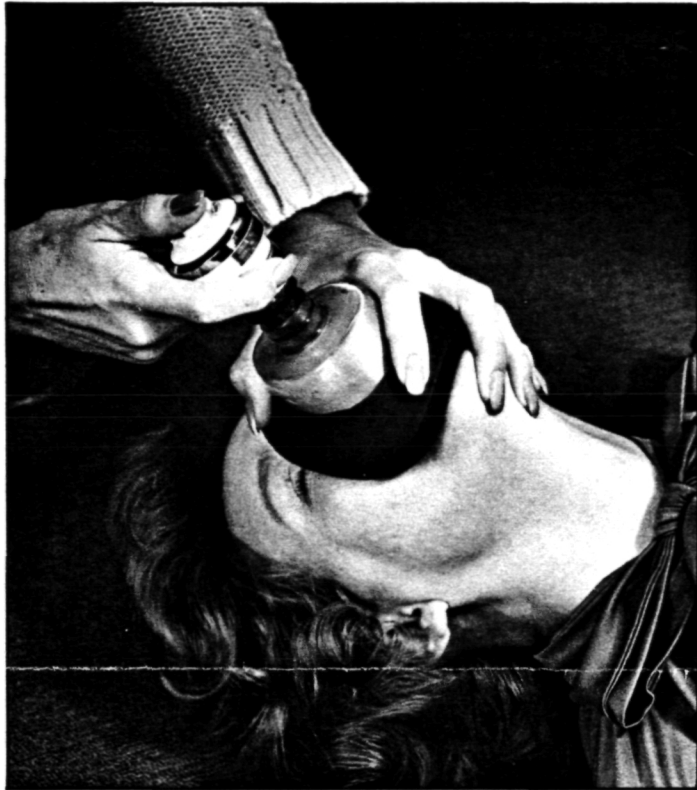


FIG. 1

This photograph demonstrates the proper method of applying the Elder Valve to a non-breathing patient. The head is fully extended. The mask is grasped firmly with thumb and forefinger. Three fingers clutch the chin, holding the head in a fully extended position. All fingers are clenched forcefully, forming an airtight mask fit. The Valve is held lightly with the other hand and pressure is applied to the manual button until the chest rises normally then released to allow passive exhalation to take place.

## DESCRIPTION

The Elder Demand Valve, Model 34, is used to provide 100% oxygen to a *breathing* or *non-breathing* patient. It is designed to operate on regulated oxygen inlet pressure between 20 to 90 psig (1.4 kg/cm<sup>2</sup> to 6.3 kg/cm<sup>2</sup>). The Valve reduces the inlet pressure to physiologically acceptable ventilation pressures. It is limited to 40 mm Hg. Variable pressures from zero to 40 mm Hg can be used depending upon the amount of pressure applied to the manual control button.

When inlet pressure is applied to the Elder Demand Valve no flow will occur until negative pressure is applied to the outlet by a breathing patient. Very slight (about 6 mm H<sub>2</sub>O) inspiratory effort produces oxygen flow. This flow increases as the inspiratory effort increases and stops flowing when this effort stops.

To resuscitate a non-breathing patient, the Elder Demand Valve is designed for use with a face mask, endotracheal tube, esophageal airway, or tracheostomy tube. When connected to the breathing system of a non-breathing patient with one of these modes, oxygen will flow to the patient and inflate the lungs when the manual button is depressed. Only enough effort should be applied to the button to ensure a normal movement of the chest. The resulting pressure will be maintained until the manual control is released. Passive exhalation then takes place through the non-rebreathing valve.



FIG. 2

This photograph shows how to use the Valve with a trigger arm installed. The method is essentially the same as in Fig. 1, but allows the operator to use both hands to hold the neck extended and operate the manual control button with a finger at a position just above the face mask. This method is especially effective for people with small hands.

The Elder Demand Valve is also used to ventilate a patient in conjunction with Cardiopulmonary Resuscitation (CPR).

## OPERATION

1. Connect the pressure hose to an oxygen supply source capable of delivering 140 to 620 KPa (20 to 90 psi) to the Elder Demand Valve and turn oxygen supply to ON.
2. Apply the Valve with one of the designed modes to the airway entry and tilt the head back as described in figs. 1 & 2.
3. If no inflation of the lungs occurs, an obstruction to air passages should be suspected. Such an obstruction must be cleared before ventilation can be effective.
4. Press the manual button until the chest rises to ventilate, then release the button to allow passive exhalation to occur. The breathing cycle of an adult is 12 to 15 times per minute, 15 to 20 for children, and 25 to 35 for infants.

## SPECIFICATIONS

Inlet pressure: 140 to 620 KPa (20 to 90 psi).

Temperature: -40° ± C to 100°C (-40°F to 212°F)

Flow: 85 lpm at 140 KPa at 140 KPa to 350 lpm at 620 KPa (approx.).

Inspiratory effort at 345KPa: 50mmH<sub>2</sub>O ± 15 Pa to start flow, flows 1pm at 220 PaH<sub>2</sub>O ± 20mm Pa straight line curve to maximum flow.

Pressure range and limit to pulmonary system: 0-40 mm Hg.  
 Maximum escape volume before pressure equalization when charging  
 Valve: 45 ml.  
 Filtration: 4 micron sintered stainless steel, effective filtration area .94 in.<sup>2</sup>  
 (6.0 cm<sup>2</sup>).  
 Weight: 3.5 oz (99 g.).  
 Materials: "Noryl" plastic, polyester, polycarbon. Metal: moving and adjusting parts are all stainless steel; fastening parts are steel, brass and aluminum which are all plated for corrosion resistance. Rubber parts are all silicone except hose.  
 Corrosiveness: None.  
 Hose burst pressure: 1,000 psi (70 kg/cm<sup>2</sup>).  
 Hose fittings: DISS, 'O' rings for finger tightening.  
 Downstream Housing: 22 mm O.D. x 15 mm I.D.

#### CLEANING PROCEDURE

The following methods may be used to clean and sterilize the Elder Demand Valve:

1. Downstream Housing and Diaphragm Assembly may be boiled as a method of sterilization.
2. Gas sterilization - all components may be sterilized by ethylene oxide techniques provided the sterilizer temperature does not exceed 200°F.
3. Cidex may be used to sterilize the Downstream Housing and Diaphragm Assembly, masks or other modes of airway entry. They should be immersed in a solution of Cidex for a minimum of 15 minutes. After removal from the Cidex solution the parts should be thoroughly rinsed and completely dry before reassembly.
4. Completely and carefully examine the Downstream Housing and Diaphragm Assembly. Discard any cracked or damaged parts and replace with new parts.
5. Soap and water or alcohol may also be used to clean Valve.
6. Before returning Valve to use, it should be checked to see that its maximum output pressure is approximately 40 mm Hg. Use Elder Test Lung part #34-575 or test manometer part #34-576. It is recommended that each Elder Valve be checked for pressure compliance at least once every 3 months.

#### WARRANTY

The Elder Demand Valve will be free of material and workmanship defects for a period of two (2) years with the exception of rubber parts which are warranted for one (1) month.

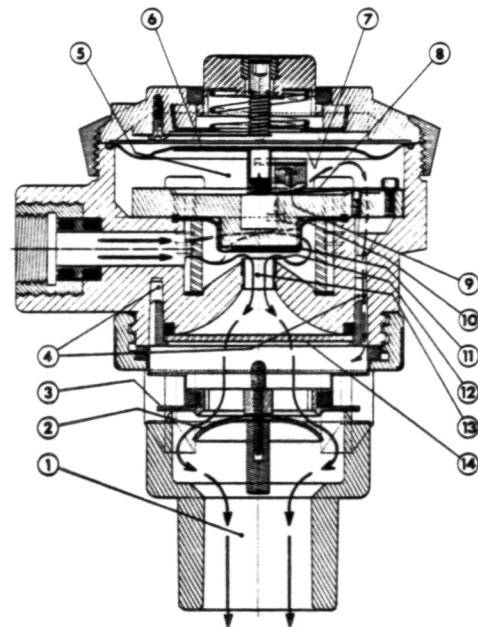
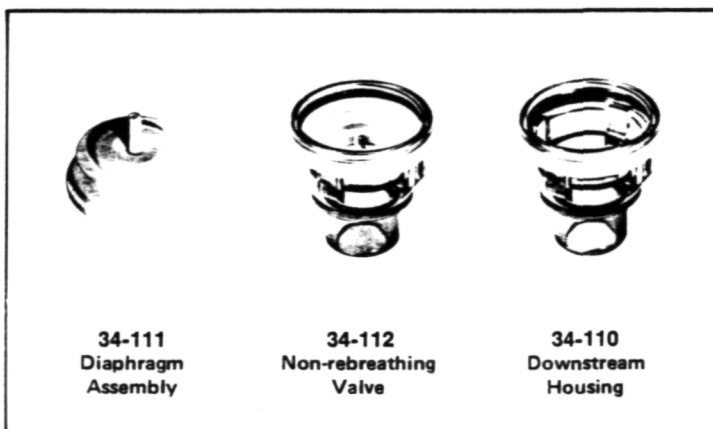
#### RECOMMENDATION:

It is recommended that a spare Non-rebreathing Valve Diaphragm Assembly Part No. 34-111 be kept available for each Elder Valve in service.

#### WARNING

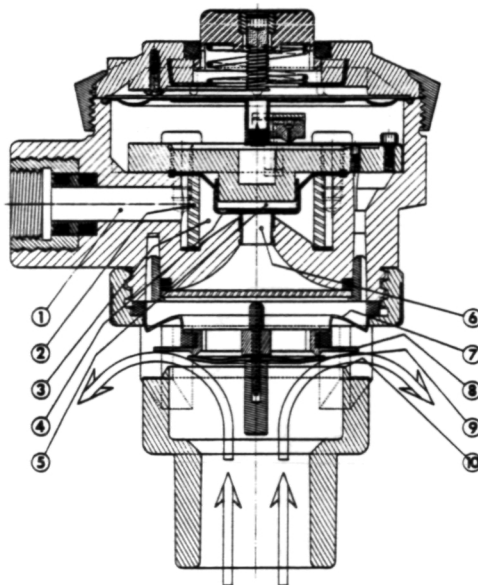
The above warranty will become void if the Valve assembly shows any evidence of tampering or forceful entry into the internal portion of the Demand Valve. Should a malfunction occur, the Demand Valve should be returned to the factory for repair.

\*Note: When ventilating an apneic patient with an Elder Valve (usually when tubed) you may occasionally notice a noise during passive exhalation which we describe as chattering. This is caused by the turbulent flow of the venting gases into the restricted chamber distal to the disc of the Diaphragm Assembly (see schematic). This in no way affects the function of the Valve. To alleviate this noise, back off about one-half turn on the Downstream Housing.



**INHALATION:** Patients inspiratory effort 1 creates a sub-atmospheric (negative) pressure which opens rubber mushroom valve 2 closing sealing disc 3 preventing room air from entering system; negative pressure is channeled through conduits 4 into negative pressure chamber 5 causing rubber sensing diaphragm 6 to deform; carrying paddle 7 to deflect leaf spring 8 which opens seal of jet nozzle 9 to flow through .0071 in. (.18 mm) Dia. orifice. The flow reduces pressure in main valve chamber 10 which opens main 11 valve from knife edge 12 allowing pressurized gas to flow through flow channel 13 into diffusion chamber and exhausts into the patients pulmonary system through laminating filter 14.

When the patient is not breathing a similar breathing effect is simulated by pressing the manual control button on the Valve. The maximum pressure is limited to 40 mm Hg. A lesser pressure from 0-40 Hg can be achieved with a lighter pressure on the manual control button.



**PRESSURE EQUALIZATION:** Oxygen enters Valve from supply source 1 is filtered through a 2 micron particle sintered stainless steel filter with 6.45 cm<sup>2</sup> (1 in.<sup>2</sup>) surface area 2 pressurizing flow cavity 3 passing through .14 mm (.0055 in.) Dia. orifice 4 into main valve cavity 5 equalizing pressure between 3 and 5 sealing off flow channel 6. If the supply is turned on slowly there is no gas escape during equalization. If turned on as rapidly as possible not more than 50 ml escapes during equalization.

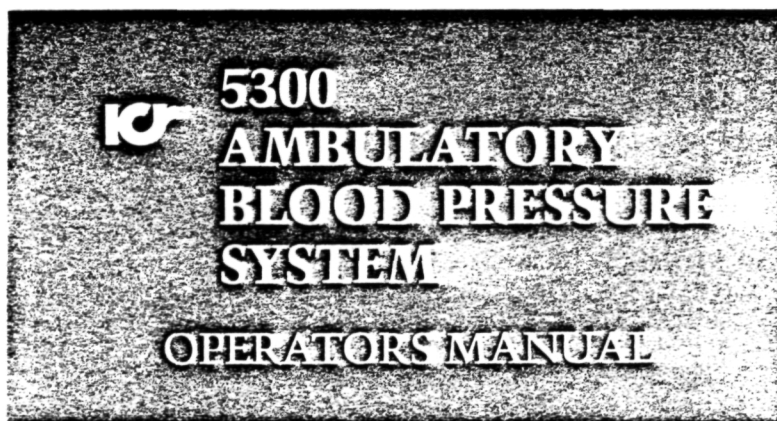
**EXHALATION:** Rubber diaphragm 7 lifts, closing rubber mushroom valve 9 which bars exhaled gas from entering Valve mechanism; carrying sealing disc 8 away from knife edge 10 allowing exhaled gases to vent to atmosphere.

## 7.5 Manufacturers Instruction Manuals



# Spacelabs

A Squibb Company



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070-0018-00A

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## **MANUAL CHANGE INFORMATION**

At Spacelabs, we continually strive to keep up with latest electronic developments by adding circuit and component improvements to our instruments as soon as they are developed and tested.

Sometimes, due to printing and shipping requirements, we can't get these changes immediately into printed manuals. Hence, your manual may contain new change information on following pages.

A single change may affect several sections. Since the change information sheets are carried in the manual until all changes are permanently entered, some duplication may occur. If no such change pages appear following this page, your manual is correct as printed.

# SPACELABS MANUAL CHANGE INFORMATION

: PRODUCT 5300	EFF SN ALL	CHANGE REFERENCE C1
: MANUAL NO. 070-0018-00A	DATE 5/21/84	LOCATION RAM PACK BATTERIES

## CAUTION

If the RAM Pack batteries are extremely low, the monitor will not always show L L L for low battery. 88.8 or 88.0 will be displayed in most cases when the batteries are too low for the monitor to operate.



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## SAFETY SUMMARY

The general safety information in this summary is for both operating and service personnel. Specific **WARNINGS** and **CAUTIONS** will be found throughout the manual where they apply, but may not appear in this summary.

### Terms In This Manual

**CAUTION** statements identify conditions or practices that could result in damage to the equipment or other property.


**WARNING** statements identify conditions or practices that could result in personal injury.


### Terms As Marked On Equipment


**CAUTION** indicates a personal injury hazard not immediately accessible as one reads the marking, or a hazard to property including the equipment itself.

**DANGER** indicates a personal-injury hazard immediately accessible as one reads the marking.

### Symbols As Marked On Equipment

 **DANGER** — High voltage.

 Protective ground (earth) terminal.

 **ATTENTION** — refer to manual.

### Make Periodic Safety Inspections

Inspect the power cord periodically for fraying or other damage, and replace as needed. Do not attach the apparatus to mains power with a damaged power cord or plug.

Before each use, check the microphone cable and air hoses for breaks or excess wear.

### Power Source

This product is intended to operate from a power source that does not apply more than 132 volts rms between the supply conductors or between either supply conductor and ground. A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation.

The product is compatible with isolated power systems as used in operating rooms.

### Use The Proper Power Cord

Use only the power cord and connector specified for your product. Use only a power cord that is in good condition.

This product requires a three-wire (18-gauge, SJT-grade) power cord which is supplied (in U.S.A and Canada) with a three-terminal polarized plug (Hospital Grade) for connection to the power source and protective ground. The ground (earth) terminal of the plug is directly connected to the frame of the product. For electric shock protection, insert this plug only in a mating (Hospital Grade) power outlet with a protective-ground contact. Do not bypass the grounding connection. Any interruption of the grounding connection can create an electric shock hazard.

### Use The Proper Fuse

To avoid fire hazard, use only the fuse specified for your product, identical in type, voltage rating, and current rating.

### Service

Component replacement and internal adjustments must be made by qualified service personnel only.

### Use Only Recommended Accessories

To ensure patient safety, use only recommended accessories. For a list of those accessories for use with this product, see the Accessories Section.

### Use Only Recommended Sterilization Methods

**Do not autoclave this product.**

Do Not Autoclave Accessories unless the manufacturer's instructions clearly approve it. Many accessories can be severely damaged by autoclaving.

A product that has been dropped or severely abused should be checked by qualified service personnel to verify proper operation.

## CAUTIONS

Listed below are CAUTIONS statements in this manuals.

### CAUTION

*Turn off the Power Switch on the monitor or POS before inserting or removing the RAM Pack. See Section 3, Operation, Preparing For Testing.*

### CAUTION

*If you press the MENU or BREAK key, all measurement data stored in the mini-computer will be erased. You must reload the data from the RAM Pack or cassette tape. See Section 2, Description, POS Computer.*

### CAUTION

*Cassettes recorded on one Portable Operating Station should be played only on that Operating Station. A cassette recorded on one POS might not be readable on another POS: data may be lost. See Section 2, Description, POS Computer.*

### CAUTION

*Maximum recharging time is 8 hrs. More charging may damage internal batteries. Less than 8 hours shortens running time of computer. See Section 3, Operation, Recharging Batteries.*

### CAUTION

*Use only alkaline batteries in the monitor. Carbon type batteries will shorten the testing period and may cause loss of measurement data. See Section 3, Operation, Preparing For Testing.*

### CAUTION

*Save measurement data onto cassette tape and verify that it is there before reinitializing the RAM Pack. See Section 3, Operation, After Testing.*

### CAUTION

A FAILURE IN THE NORMAL OPERATION OF THE COMPUTER CAN OCCUR WHEN:

- 1) Initializing a RAM pack and entering CYCLE TIME greater than 32768.
- 2) Entering more than a total of 200 characters for PATIENT NAME + I.D. NUMBER + COMMENTS.
- 3) Reading a blank cassette.
- 4) Plugging the Ram Pack into the Portable Operating Station when the computer is on.
- 5) Bad data exists in the Ram Pack
- 6) The Ram Pack is not initialized.
- 7) Depressing the BREAK key.

When a failure does occur the computer typically reverts to the Basic program. Under certain conditions a "TRAP" will occur and normal operation can continue only after the RESET button on the rear right side of the computer has been depressed.

When the computer has reverted to the Basic program this symbol is sometimes apparent on the screen: > . To restore operation to normal, press the MENU key and continue as prescribed in the OPERATING section of this manual.

If after resetting the computer, normal operation does not continue, it may be necessary to re-load the BP MENU from the cassette into the computer. This procedure is discussed in the OPERATION section of this manual under "Loading BP MENU". If you find it necessary to re-load the program the following steps must be completed first:

- 1) Press the BREAK key
- 2) Type the word DELETE-
- 3) Press the RETURN key
- 4) Type the word TITLE" "
- 5) Press the RETURN key

Now refer to Loading BP MENU in this manual.

FOR FURTHER ASSISTANCE, CALL: 800-547-8805. Ask for Service Support.

# GENERAL INFORMATION

## INTRODUCTION

Figure 1 shows the ICR Model 5200 Ambulatory Blood Pressure Monitor. The battery powered monitor is carried by the patient on a belt and/or shoulder strap and takes blood pressure measurements using either the auscultatory or oscillometric method. (Auscultatory is used unless the unit cannot detect Korotkoff sounds, then it automatically selects oscillometric.) The Model 5250 RAM Pack, which plugs into the monitor, provides power to the monitor and stores measurement data acquired by the monitor. The RAM Pack also plugs into the ICR Model 5300 Portable Operating Station to transfer data to the Portable Operating Station.



**Figure 1. Model 5200 Blood Pressure Monitor.**

Figure 2 shows the ICR Model 5300 Portable Operating Station (POS). A battery powered mini-computer in the Portable Operating Station programs the monitor, via the RAM Pack, to take blood pressure measurements at selected intervals. After the measurement data is acquired, it is copied from the RAM Pack to the Portable Operating Station. (However, the data in the RAM Pack is not lost.) The computer in the Portable Operating Station performs various calculations on the data, and the data can be stored on microcassette tape, printed on the microprinter, or

transferred to another Portable Operating Station via the built-in telephone modem.



**Figure 2. Model 5300 Portable Operating Station.**

Batteries in the POS are recharged by the built in battery charger.

It takes both the Portable Operating Station and Monitor to take blood pressure measurements. This manual will describe the features and functions of both the Model 5300 and Model 5200. It will also instruct you how to use both units: program the Monitor, copy data from the Monitor to the POS, perform calculations on the data, and other features of the Portable Operating Station and Monitor.

## DESCRIPTIONS

### The Monitor

#### Operating Description

The Model 5200 Monitor can record systolic pressures between 70 and 270 mmHg and diastolic pressures between 40 and 155 mmHg. The monitor will start in the auscultatory mode and pump up the cuff to 160 mmHg. If Korotkoff sounds are present, they are detected by a microphone in the cuff, and the pressure is increased in steps of 25 mmHg until no sounds are detected. When this stage is reached, the cuff is deflated in steps of 3 to 5 mmHg. As Korotkoff sounds are again detected, the pressure is read as the systolic pressure.

When regular sounds are heard, heart rate is measured.

The monitor now drops the pressure rapidly to about 90 mmHg and then continues to drop pressure in steps of 3 to 5 mmHg until Korotkoff sounds are no longer detected. This is taken as the diastolic pressure. On subsequent measurements, the monitor pumps the cuff to 25 mmHg above the last systolic pressure.

The highest pressure that the monitor can achieve is about 290 mmHg.

If the microphone is inoperative, or if no Korotkoff sounds can be detected, the monitor will measure pressure by the oscillometric technique — by monitoring the pressure oscillations in the cuff.

The difference between the two methods can be heard. When in auscultatory mode, after the cuff has occluded the artery, the monitor releases 3-5 mmHg at a time until it detects the systolic pressure. Then it drops to about 90 mmHg. This drop is quite noticeable from the 3-5 mmHg pressure drops. In oscillometric mode, the pressure is dropped in 3-5 mmHg increments throughout the measurement.

As in the case of manual methods, accurate readings may not always be achieved under some conditions. Excessive patient movement, extreme heart rates and blood pressures, and various types of arrhythmias are examples of patient conditions which may hinder a reading. Ambient noise and/or vibrations, such as those in a moving automobile, are environmental problems which may also affect readings. Under conditions where the monitor cannot measure pressure, trained medical personnel would also have difficulty.

When conditions prevent completion of a blood pressure measurement, an error code will appear on the monitor display screen. The monitor will attempt another measurement in 60 seconds. If a measurement

is not attainable, the monitor will take a measurement at the next programmed time.

#### Controls, Connectors, and Indicators

The Model 5200 Monitor weighs about four pounds. It is strapped to the patient by a shoulder strap or by a waist belt (Figure 3). Blood pressure measurements are taken using an inflatable cuff containing a microphone (Figure 4). Following are descriptions of the connectors, controls, and indicators. Refer to Figure 5.

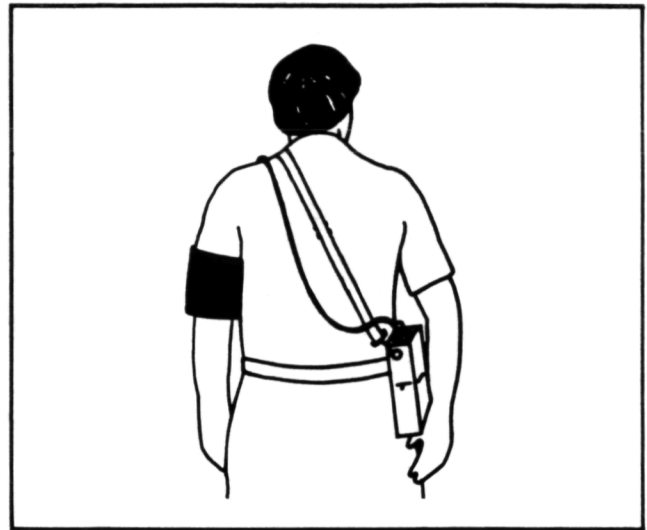


Figure 3. Monitor on patient.



Figure 4. Cuff and Microphone.

#### 1 CUFF CONNECTIONS

The cuff attaches to the Monitor via two hose connectors and the microphone connector. Hose connection orientation is not important, but the microphone connector has an index so that the microphone can be plugged in only one way. The microphone connector also has a safety ring which secures the microphone.

## Descriptions—5300

The connector is disconnected by pulling out on the ring of the connector where it connects to the monitor.

### 2 DISPLAY

The Monitor display is activated when the 5200 is initialized. The display shows first the systolic pressure (a short horizontal bar appears in the upper left corner of the screen), then the diastolic pressure (the bar moves to lower left corner), and heart rate (bar goes to center-left) each time a measurement is taken. The display also provides a five-second countdown before taking a pressure and displays error codes when problems occur.



Figure 5. Monitor Controls, Connector, and Indicators.

### 3 CONTROL SWITCHES

Two switches to the left of the display turn on or off the monitor (OFF/ON) and provide for manual control of starting or terminating a blood pressure measurement cycle (START/STOP).

#### CAUTION

*To prevent improper initialization or loss of data, turn off Power Switch before plugging in or unplugging a RAM Pack.*

### 4 RAM PACK

See Figure 6. The RAM Pack plugs into the rear of the monitor. This is a plug-in unit which stores the measurement data and provides battery power to the monitor. The RAM Pack is also plugged into the POS for initialization, and after data is acquired, it is again plugged into the POS to copy the data from the RAM Pack to the POS computer.

#### CAUTION

*To prevent improper initialization or loss of data, turn off Power Switch before plugging in or unplugging a RAM Pack.*

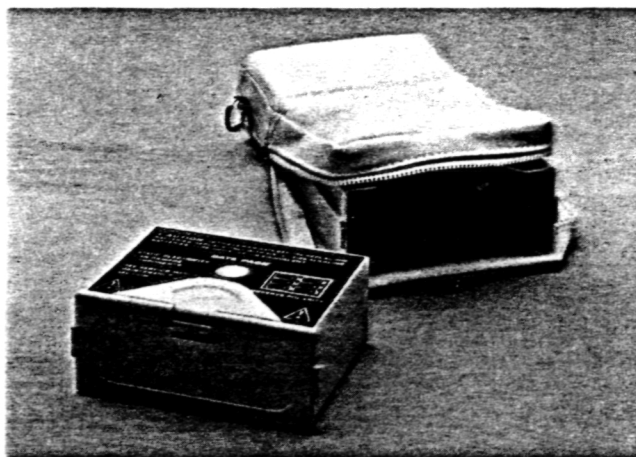


Figure 6. Ram Pack and Monitor Connector.

The monitor carrying case unzips to allow access to the RAM Pack.

A shoulder strap connects to the monitor carrying case at two clip rings. A waist belt loops through the monitor carrying case.

## The Portable Operating Station

The Portable Operating Station contains four units (Figure 7). They are the POS Computer, the telephone modem, the interface circuit board located inside the POS, and the battery charger. Near the battery charger are the communication connectors: labelled TO COMPUTER and TO MODEM.



Figure 7. Portable Operating Station.



## POS Computer

See Figure 8. The POS Computer contains 16K of memory, a built-in microprinter for hard copy, and a microcassette drive for data and program storage.



Figure 8. POS Computer.

### 1 POWER SWITCH

The Power Switch turns on and off the power to the POS (except the telephone modem).

#### CAUTION

*To prevent improper initialization or loss of data, turn off Power Switch before plugging in or unplugging a RAM Pack.*

### 2 VIEW ANGLE ADJUSTMENT

The LCD screen has a very narrow viewing angle. Turn the View Angle adjustment until the screen displays a normal display. The screen should be viewed only from the front of the POS. The View Angle Adjustment may not help when viewing from the side.

### 3 RESET

The Reset button clears the computer's temporary memory and sets the computer to the main (power-up) menu. But the BP MENU program is not erased. If there was measurement data stored in the computer, you will have to reload that data into memory.

### NOTE

*If the computer ever stops operation and nothing you try helps, press RESET. But, use RESET only when absolutely necessary. If you press RESET, ALL MEASUREMENT DATA IS ERASED. If RESET doesn't start the computer operating normally, reset the date/time clock using the CTRL @ function. You will then need to reload the BP MENU program from cassette tape. See LOADING BP MENU.*

### 4 PAUSE KEY

The Pause key stops a running program and also stops the display from scrolling. This is useful if, for example, something appears on the mini-computer display which would scroll out of sight before you could read it.

Press any key to cancel pause mode.

### 5 MENU KEY

The Menu key, when pressed, stops the BP MENU program and returns the computer to the main (power-up) menu.

### 6 BREAK KEY

The Break key, when pressed, stops the BP MENU program; the computer remains in BASIC mode. To restart the BP MENU program again, type RUN and press RETURN or press the MENU key and select BP MENU (number 3).

#### CAUTION

*If you press the MENU or BREAK key, all measurement data stored in the mini-computer is erased. You must reload the data from the RAM Pack or cassette tape.*

For more information about the POS mini-computer, see your Epson Computer manuals.

### 7 MICROPRINTER

The computer's microprinter provides a hardcopy of measurement data. To operate, the PRINTER ON/OFF switch must be turned on. The PAPER FEED button advances the printer paper one line at a time.

## 8 MICROCASSETTE DRIVE

The microcassette drive writes to and reads from microcassettes. The red light turns on when the cassette is recording. If the cassette drive cover does not close easily with a cassette in it, do not force it. Remove the cassette and try again.

## 9 EJECT BUTTON

Slide the CASSETTE EJECT button backwards to eject the cassette.

### CAUTION

*Cassettes recorded on one Portable Operating Station should be played only on that Operating Station. A cassette recorded on one POS might not be readable on another POS; data may be lost.*

## Telephone Modem

The modem (Figure 9) provides two way communication between two Portable Operating Stations. The modem is under program control and operates at 300 baud, no parity, 8 data bits, and 2 stop bits. How to use the modem is covered in TRANSFERRING DATA of the Operating Section. Following are descriptions of its switches and the modem connector.

### 1 MODEM CABLE CONNECTOR

The modem is connected to the modem connector located next to the battery charger (labelled TO MODEM). When communicating over the modem, connect the modem cable (supplied with the POS) to the modem connector and connector labelled TO COMPUTER.

### 2 POWER SWITCH

The modem is turned off and on by the Power Switch. The modem is powered by its own rechargeable batteries; it is not powered by the mini-computer.

### 3 ORIG/ANS SWITCH

This switch sets the modem's operating mode. In ORIG mode, the modem sends data. In ANS mode, the modem receives data. You will most often use the ORIG mode.

### 4 HALF/FULL DUPLEX SWITCH

Set this switch to FULL. Half Duplex is not used. This switch also has a TEST mode. See Troubles? Section for information on using the TEST mode.

## Battery Charger

See Figure 10.

The batteries in both the modem and computer are rechargeable. When the POS Computer's battery voltage is low, the POS Computer displays RECHARGE BATTERIES. The batteries must be recharged. (Both POS Computer and modem batteries are recharged at the same time.) See Recharging Batteries in the Operating Section.

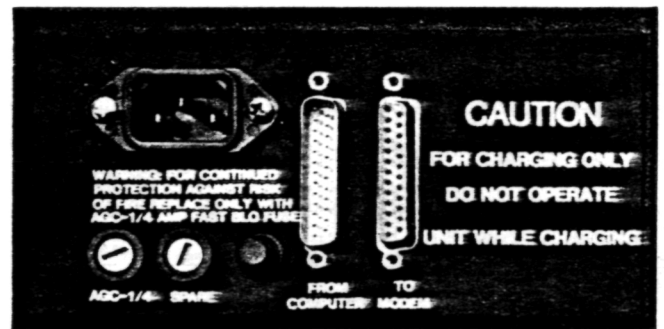


Figure 10. Battery Charger.

### CAUTION

*Maximum recharging time is 8 hours. More charging may damage internal batteries. Less than 8 hours shortens running time of computer. See Section 3, Operation, Recharging Batteries.*

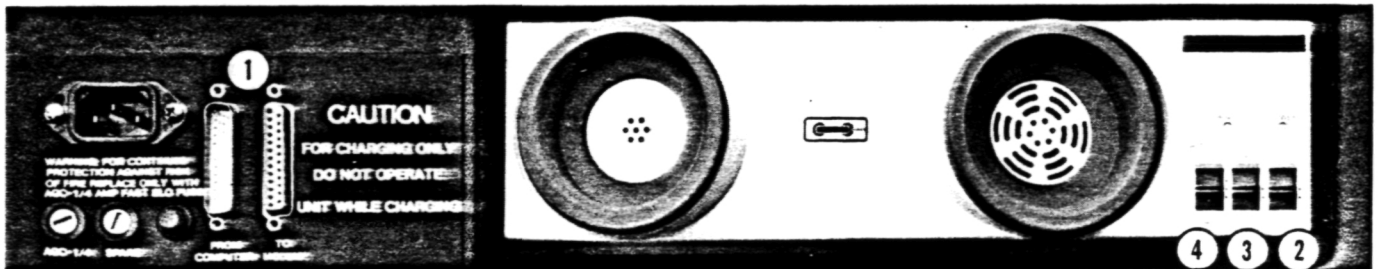


Figure 9. Telephone Modem.



## Interface Board

See Figure 11.

The Interface Board allows communication between the RAM Pack and the POS computer. The board and its connector are mounted in the suit case.

### CAUTION

*To prevent improper initialization or loss of data, turn off Power Switch before plugging in or unplugging a RAM Pack.*



Figure 11. Interface Board Connector.

## OPERATING SPECIFICATIONS

### Controls, Connectors and Indicators

#### ON/OFF

Two position slide switch.

"ON" — Normal operation — allows monitor to cycle on pre-programmed time intervals.

"OFF" — Standby mode, no cycling occurs, data retained.

#### START/STOP

Pushbutton depressed to begin manual blood pressure measurement if none in progress overrides present cycle time, and resets timer.

If depressed during blood pressure measurement, unit will abort cycle.

#### AUDIO

Audible tone indicates start of a cycle or an error code has been obtained.

### General

#### MEASUREMENT RANGES

Heart Rate: 40 to 180 bpm; pressure 70 to 270 mmHg for systolic, 40 to 150 mmHg for diastolic, and 50 to 180 mmHg for mean arterial values. Monitor is designed to operate between 40 to 280 mmHg. Clinical tests have verified accuracy in accordance with proposed AAMI standards.

#### PRESSURE MEASUREMENT METHOD

Auscultation method when Korotkoff sounds are audible, with a back-up method of oscillometry when Korotkoff sounds cannot be heard.

#### AUTOMATIC MEASUREMENT INTERVALS

Physician may adjust time interval from six minutes minimum to 60 minutes maximum, by preprogramming RAM PACK. These cycles can be preprogrammed to change during the day and night to more frequent or less frequent time intervals.

#### MEASUREMENT CYCLE TIME

Typically 20-50 seconds; cuff inflated to pressure mmHg for no longer than 90 seconds.

#### MAXIMUM CUFF PRESSURE

$300 \pm 10$  mmHg

#### AUTOZEROING

Pressure transducer channel automatically zeroed before each reading.

#### ARTIFACT REJECTION

Microprocessor program discriminates between pressure signals and extraneous sounds, such as patient movement.

#### CUFF INFLATION/DEFLATION

Automatic, motor driven pump operation. Deflate rate under microprocessor control.

#### DATA STORAGE SYSTEM

Nonvolatile CMOS 2K RAM, located in battery pack. Information retained until batteries are replaced. Timing of events provided by real time clock in battery pack.

#### DIGITAL DISPLAY

3 digit, 7 segment, liquid crystal display. Systolic, diastolic, and heart rate information to be alternately displayed. Blinking cursor provided to indicate when unit is on.

#### PATIENT SAFETY

Measurement cycle under 90 second timing control. Pneumatic system open when off. Air harness detachable at cuff. Independent over pressure sensor to interrupt system at 300 mmHg. 510K approval.

### Physical

#### POWER REQUIREMENT

Replaceable battery pack consisting of six C-size, non rechargeable batteries.

#### DIMENSIONS

8.60"L  $\times$  4.75"W  $\times$  1.95"D

#### WEIGHT

Monitor, vinyl bag and batteries — 3 lbs. 9 oz.

# OPERATION

## Getting Started

### The Mini-computer

In this section you'll be learning how to find your way around the POS computer. You'll also learn how to keep your POS computer batteries in optimum shape and how to change the printer ribbon and printer paper. Briefly, the computer has four operating modes: initializing mode, monitor mode, BASIC mode, and BP MENU mode. When you turn on the computer you can pick any one of these.

### MONITOR MODE

First, the Monitor mode. If you enter it, the screen will look like Figure 12. The only important thing to know is how to get out of it if you get into it. Monitor mode is not used for BP MENU operation. The way to get out is to press the MENU key.



Figure 12. Monitor Mode Display.

### DATE/TIME SETTING MODE

Second is the initializing mode or date/time setting mode. This mode is to set the date/time clock in the computer. To enter the date/time you must be at the main (power-up) menu, which is shown in Figure 13. Hold down the CTRL(CONTROL) key and press the @ key. (Release the CTRL and @ keys.) A display as shown in Figure 14 tells you to enter the date and time as MMDDYYHHMMSS. (To get out of this mode without setting time, press the BREAK key.)

The clock is a twenty-four hour, date/time clock. You must enter the time in military time. You must also enter two digits for each time as shown in Figure 15. If you don't, the computer will remain in the initializing mode until you press either the BREAK or MENU key, or until you enter the date/time properly.



Figure 13. Main (Power-up) Menu Display.

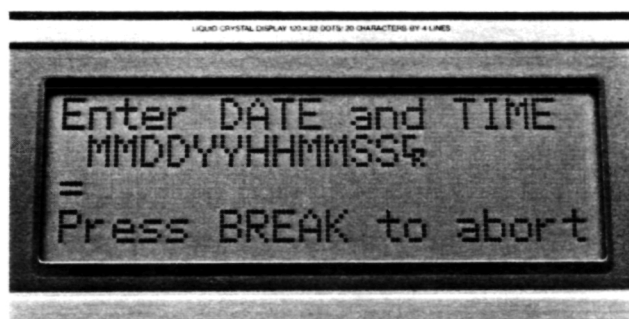


Figure 14. Date/Time Menu Display.



Figure 15. Date/Time Entered.

When entering the date/time, do not enter slashes (/) or dashes (-). Just enter the date/time as one long string. Then press RETURN. The computer's clock is all set.

### NOTE

*When you initialize the computer, the BP MENU program is erased. You must reload it as described in LOADING BP MENU.*

The date and time is copied to the RAM Pack when initializing the Pack.

## BASIC MODE

BASIC mode runs programs written in BASIC programming language. If you use BASIC mode without consulting your Epson Computer manuals, it is possible to erase or destroy the BP MENU program. Do not use BASIC mode unless you fully understand how the POS Computer operates and how to program it.

## BP MENU MODE

BP MENU runs the 5200 and 5300. Operating instructions are covered in this manual.

More detail on the computer and its capabilities will be found in the Epson Notebook Computer Operations Manual. Learning how to program in BASIC is taught in the BASIC manual, Volume 1. Volume 2 is the BASIC Reference Manual. The Microcassette Drive is covered in its own manual. See those documents for further detail on those subjects. Read on for information about BP MENU.

## Recharging Batteries

Recharge the batteries only when the mini-computer displays RECHARGE BATTERIES. The Battery Charger recharges both the mini-computer and modem batteries. Recharge batteries for only 8 hours. You may plug the battery charger into an 8 hour timer to prevent overcharging.

To recharge batteries:

1. Turn off mini-computer and modem power switches. If a RAM Pack is installed in the Interface Board, remove it after the power is turned off.
2. Remove the 3-wire ac power cord from the cover of the POS. Plug it into the Battery Charger and a 3-wire, grounded ac outlet. Do not use a 3-wire to 2-wire adapting plug — it violates safety regulations and may void your warranty.
3. Charge batteries for eight hours. Do not overcharge or undercharge. You may plug the battery charger into an 8 hour timer to prevent overcharging.
4. Do not use the POS during recharging unless it is absolutely necessary.
5. If there is data in a RAM Pack, the RAM Pack will retain its data while the POS is recharging.

## Changing Printer Ribbon

1. See Figure 16. Press on the ribbon cover (in front of the slot where printer paper exits) where it is labelled PUSH. The cover pops up. Remove it and set aside.



Figure 16. Removing Printer Ribbon Cover.

2. Press on the ribbon where it is labelled PUSH. The ribbon pops out.
3. Slide in the new ribbon, right end first.
4. Snap the ribbon cover in place.

## Changing Printer Paper

1. See Figure 17. With your finger nail in the slot, press back and up. Cover tilts backward exposing paper compartment.



Figure 17. Opening Paper Compartment Cover.

2. Remove old paper roll. If necessary, discharge the paper in the printer by pressing and holding the PAPER FEED button. Lay out flat the blue ribbon in the compartment.

3. Holding paper as shown in Figure 18, slide end of paper into slot in front wall of paper compartment. Press PAPER FEED button.



Figure 18. Loading Printer Paper.

4. Paper will feed up into printer and out through top of ribbon cover. Set paper roll in the compartment. Close the cover.

## Loading BP MENU

See Figure 19. BP MENU is the name of the program which runs the Portable Operating Station. It contains the programming to initialize the portable monitor, copy the acquired data from the RAM Pack to the computer, perform calculations from the data, copy the data to the cassette tape or microprinter, and send the data to another Portable Operating Station.



Figure 19. Main (Power-up) Menu Display.

BP MENU is loaded into the computer at the factory. When properly installed, the words BP MENU appear

in the main (power-up) menu. If BP MENU does not reside in your computer, you can load it from the cassette tape provided with the POS. Once BP MENU is loaded as described below, you can select the program from the main (power-up) menu.

To load BP MENU from cassette tape follow these instructions:

1. From the main (power-up) menu select BASIC (2). BASIC copyright and status are displayed.
2. Insert BP MENU tape into cassette drive.
3. Type WIND and press RETURN.
4. Type LOAD and press RETURN. The computer will display Searching. When it has found the BP MENU program, it will display Found: BP MENU.
5. When BP MENU is loaded, the BASIC prompter (>) will be displayed.
6. Protect the program by typing TITLE"BP MENU" and press RETURN.
7. Now either go back to the main menu and select BP MENU or type RUN and press RETURN. The program will run.

BP MENU has several operations and displays several menus depending on the function to be performed. The main program menu, called the BP MENU, is shown in Figure 20.



Figure 20. BP Menu Program Menu.

These basically are the four operations of the BP MENU program. It can initialize the monitor's RAM Pack, copy (read) the data in the RAM Pack to the computer, save the data onto the microcassette tape, and display the data on the screen or microprinter. Other options are available in the program as discussed later. From the BP MENU, whatever selection you make will produce another menu, thus making BP MENU very easy to use.

## Preparing For Testing

In this section you will be instructed how to set up and initialize the RAM Pack for testing and instruct the patient what to do.

Following are instructions on how to initialize the RAM Pack.

1. Open the RAM Pack by sliding a quarter into the slot on the back end of the Pack.
2. Install six new C-size, alkaline batteries into the RAM Pack. These are provided with the Patient Kit.

### CAUTION

*Use only alkaline batteries. Carbon type batteries will shorten the testing period and may cause loss of measurement data.*

3. Turn off POS computer power switch. Place the RAM Pack into the interface board slot in the Portable Operating Station.
4. Turn on the computer. Select BP MENU and then INIT RAM PACK. Now the computer will ask you several questions.
5. DISPLAY ACTIVE ON MONITOR (Y/N) = Do you want the monitor to display the blood pressure readings and heart rate for each measurement? Type Y for yes, N for no.
6. SINGLE OR MULTIPLE CYCLE TIMES (S/M)? = Do you wish the monitor to take measurements at the same interval throughout the testing period or do you want to select different intervals? Type S for single or M for multiple.
7. If you type S, the computer will ask for the interval. You may select intervals between 6 and 60 minutes. Any number above 60 sets the interval to 60; any number below 6 sets the interval to 6. After the interval is entered, the computer displays ALARM ON? This means, Do you want the computer to sound an alarm five seconds before the next measurement to notify the patient of? Type Y for yes, N for no.

8. If you select M, the computer will ask you to enter measurement intervals for six-hour periods starting at 0000 hours (midnite) and ending at 2359 hours (11:59 PM). For each six-hour period the computer will also ask you if you want the audible alarm to sound as mentioned above in item 7. You may not want the interval the same at night as during the day. And you may not want the alarm to sound if the measurements are taken while the patient sleeps.

9. Finally the computer asks for the patient name, ID code and any comments. When all this is entered, press RETURN. The RAM Pack is now initialized. To verify that it is initialized, follow these simple steps:

- a. Select READ DATA from the BP MENU
- b. Select READ RAM PACK. When reading is done screen displays BP MENU.
- c. Select DISPLAY DATA.
- d. Select LIST DATA.
- e. Select ALL DATA.

The printer prints the patient name, ID Code, and date. If any of this information is incorrect, (1) turn off the mini-computer's power, (2) remove the RAM Pack, (3) remove the RAM Pack batteries, (4) wait five minutes and either replace the batteries or install new ones, (5) reinitialize the RAM Pack. If there still are errors, try another RAM Pack or have the units serviced by qualified service personnel.

10. Once the RAM Pack is initialized, turn off the mini-computer's power, and remove the RAM Pack. Make sure the monitor's power switch is off and reinsert the pack into the monitor. Zip up the carrying case.
11. Turn on the monitor and allow a few seconds for it to perform self diagnostics. In a few seconds the screen will display 000 meaning everything checked out ok. A blinking cursor indicates that the monitor is turned on.
12. Strap and/or belt the monitor to the patient on the hip opposite the side which will have the cuff.



13. Select the proper size of cuff. This is very important. The air bladder in the cuff must wrap at least half way around the limb. If the cuff is too small, pressure readings may be falsely high, too large of cuff produces falsely low readings.

Make sure all air is removed from the cuff.

Cuff Size	Limb Circumference
Standard Adult	25-35 cm
Large Adult	33-47 cm
Pediatric (or thin adult)	18-26 cm

14. Check that the microphone is properly positioned in the cuff. The microphone is labelled "to arm" on one side. It is suggested that you leave the microphone inside the cuff rather than remove it and tape it to the patient's arm. Removal may place excess strain on the microphone cable causing breakage.

Instead, mark the patient's arm above the brachial artery and place the microphone in the cuff over the mark. Have the patient periodically check, and, if necessary, readjust the cuff position. (This method prevents breakage due to excess strain and also allows the patient to properly reposition the cuff should it be removed.)

15. Palpate the brachial artery on the right and left arm (Figure 21[A]) and place the microphone in the cuff over it (Figure 21[B]). To avoid pressure reading errors due to hydrostatic pressure differences, the level of the cuff should be near the level of the heart. When the cuff is placed on the upper arm, the arm should be relaxed at the patient's side, not held up in the air. See Figure 21.
16. Securely wrap the cuff around the arm.

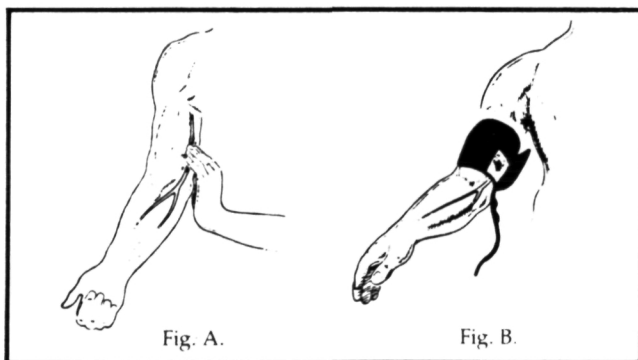


Figure 21. Proper cuff application.

17. Lead the microphone cable and air hoses up the arm and towards the back of the patient to the side opposite the arm with the cuff. See Figure 22. Drape the hoses and microphone cable so they won't cause the patient discomfort and won't be pinched around a sharp radius.

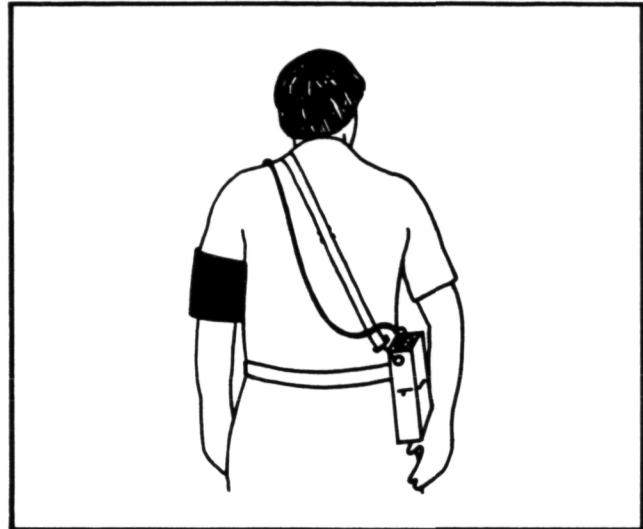


Figure 22. Positioning hoses and cable.

18. Screw the hose connectors onto the monitor. Plug in the microphone connector.
19. At this time you should verify that the monitor is operating properly. Take a manual blood pressure reading and a pressure reading using the monitor (press the START button). You can slide a stethoscope under the cuff to take the manual reading while the monitor inflates and deflates the cuff, but you must not move the stethoscope while the monitor is taking readings. Compare the two readings. If you feel there is a discrepancy between the two, check the cuff position and make sure the patient was not moving. Take pressure readings again. Record both readings in the Patient Diary on the inside cover.
20. Have the patient look over the Patient Diary. Make sure the patient knows what to do in case the cuff becomes very uncomfortable during a measurement, what to do if the cuff slips out of place, what to do if error codes are displayed on the monitor screen, and how to care for the monitor. You may want to go over the last page of the Patient Diary with the patient.

The patient is ready for testing.

## After Testing

After the testing period is over, take another blood pressure reading both manually and with the monitor. Again compare the two and record them in the Patient Diary.

### CAUTION

*Save measurement data on cassette tape and verify it is there before reinitializing RAM Pack. See Saving Data below.*

## Copying Data To POS

Once the testing period is over, follow these simple steps to copy the acquired data to the POS computer.

1. Turn off the monitor. The data in the monitor is not lost.
2. Remove the cuff and monitor from the patient. It may be more convenient to disconnect the cuff hoses and microphone cable from the monitor before removing the cuff from the patient.
3. Unzip the rear of the carrying case and remove the RAM Pack by squeezing the RAM Pack a bit and pulling straight back.
4. Turn off mini-computer's power switch. Place the RAM Pack into the interface board slot.

### CAUTION

*Turn off the mini-computer's power switch before inserting the RAM Pack into the POS or damage to the pack may result.*

5. Turn on the POS computer and select BP MENU.
6. Select READ DATA from the BP MENU.
7. Select READ RAM PACK. The screen will display READING RAM PACK.
8. If no readings were taken, the screen will display NO DATA and return to the main menu.
9. If more than 200 readings were taken, the screen will display

DATA EXCEEDS  
200 READINGS  
EXCESS LOST

The computer continues to read the data.

When it has read the data, the screen will display CALCULATING AVERAGES.

When the computer is finished it will return to the BP MENU.

## Saving Data

It is very important that you save the test data on the microcassette tape. If a Portable Operating Station is not immediately available or will not be available for some time, it is possible to keep the data in the the RAM Pack. It will retain the data for a short time (up to two days) using the batteries already in the Pack. For longer retention of data follow the instructions below for changing the RAM Pack batteries. But as soon as a POS or Analysis Station is available, save the data. If the data is not stored and if you do not verify that the stored data is correct, irrecoverable loss of your data may occur.

For retention of the data in the RAM Pack for an indefinite period of time, follow these instructions.

1. Obtain new alkaline batteries. These will be used as your "safety batteries."
2. Set the RAM Pack on a flat surface with the battery lid up. Using a quarter, insert it into the slot on the back of the RAM Pack and remove the battery lid. Do not remove the batteries yet.
3. To keep the data in the RAM Pack, you will exchange the batteries one at a time. If power to the RAM Pack is lost for more than 60 seconds, your data will be erased.
4. Remove one battery at a time and replace it with a new battery. Observe proper battery polarity. Replace the battery lid.
5. Label the RAM Pack to ensure that it is not used by mistake until the data is saved.

## Storing Data on Microcassette Tape

To save the data on microcassette tape, follow these instructions.

1. Load a blank tape into the tape drive.
2. Select SAVE DATA from the BP MENU.
3. Select DATA TO FILE. The computer will rewind the tape and load the data onto the cassette. The computer will load the same data onto the tape again in a second file. This second file is the backup data file. If for some reason the first file is not readable or contains erroneous data, the second file may be read. When the computer finishes loading the data onto the cassette, it will rewind the tape.

**NOTE**

If the computer "beeps" at you and displays "I/O ERROR...", you have probably loaded a cassette with the protection tab broken out. Use another cassette. Type RUN and press RETURN. You will then need to reread the RAM Pack or cassette tape.

4. Remove the cassette. Label the cassette tape with the patient's name and ID number. You may wish to break out the protection tab located on the right side of the cassette.

**NOTE**

If data which cannot be used has been recorded, it can be tagged so it is not displayed or used for graphic display. This operation is done using the EDIT DATA program, which is covered under EDITING DATA.

## Displaying Data

With the DISPLAY DATA program you can list the acquired data on the microprinter or plot it as a graph on the display screen or microprinter. To invoke the DISPLAY DATA program, select number four (4) from the BP MENU.

Figure 23 shows the different formats of LIST DATA and PLOT DATA.

You may either LIST DATA on the microprinter or PLOT DATA as a graph on the printer or the display

screen. These options print either all of the acquired data with the time each measurement was taken (ALL DATA), or all of the data averaged over one-hour periods (AVERAGE DATA) for a maximum of twenty-four hours. In ALL DATA the time for each measurement is printed. In AVERAGE DATA the hour over which data is averaged is printed.

LIST DATA simply provides a list showing the patient name, ID, date, the time measurements began, and a table listing the time of each measurement (ALL DATA) or the hour (AVERAGE DATA), the systolic, diastolic, and mean pressure, and the heart rate. The list also displays error codes when present. Measurements which have been deleted using the EDIT DATA program do not show up on the listing.

PLOT DATA creates a graphic display for both the ALL DATA and AVERAGE DATA selections. Figure 23 shows plots of both ALL DATA and AVERAGE DATA. Exclamation points (!) indicate the diastolic and systolic pressure readings. An asterisk (\*) on the graph indicates the mean pressure. When readings fall below the minimum value on the graph, a left angle-bracket and asterisk (<\*) are displayed under the 50 mmHg column. Some graphic indicators may not be printed when systolic, diastolic, and mean readings are too close to each other to be printed separately on the graph. Error codes do not produce graphic indicators, but the time is displayed.

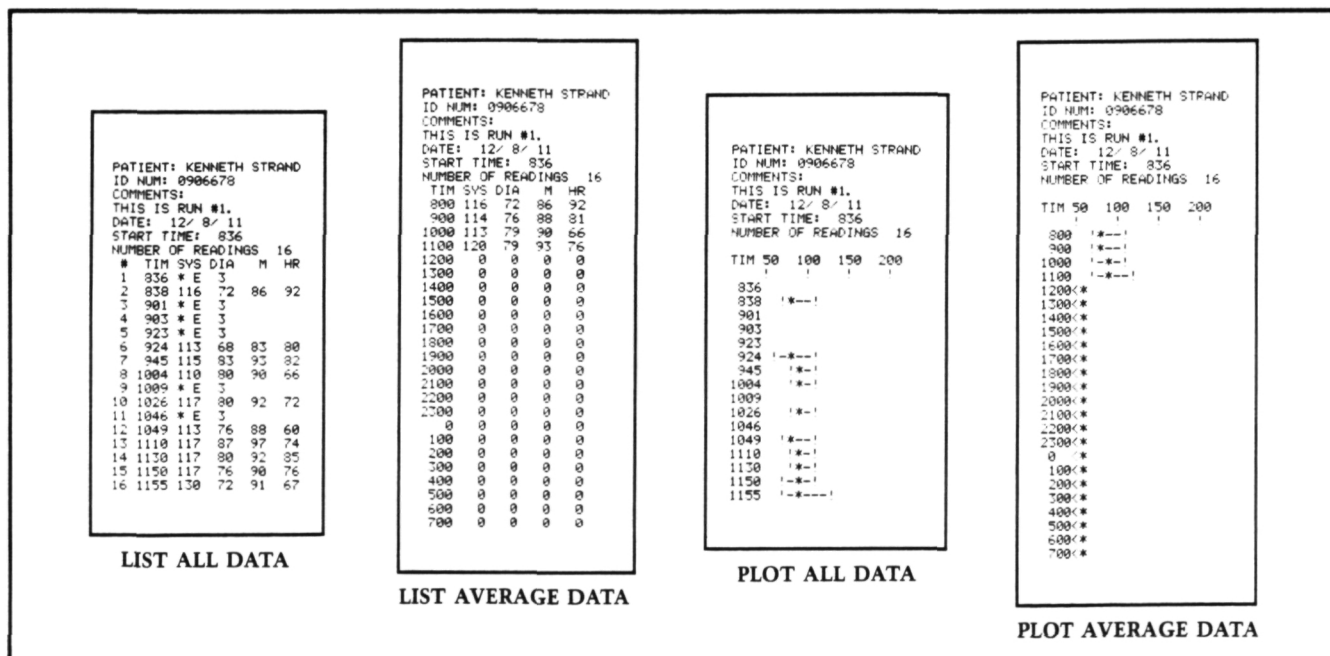


Figure 23. List and Plot Data Formats.



One feature of the PLOT DATA function is called DISPLAY DATA. This feature averages data over one-hour periods and displays the data as a bar-graph with pressure on the y-axis and time on the x-axis. The bottom of the bar represents the diastolic reading and the top indicates the systolic reading. The graph is displayed on the screen and may or may not be printed on the printer.

## Editing Data

Within the acquired measurement data may be information which is not usable such as obviously wrong systolic, diastolic, mean pressures, or heart rate, or erroneous data due to manually or automatically aborted measurement cycles. These unusable readings can be deleted from the data to make the graph and data lists more readable and to omit the readings from calculations.

The EDIT DATA program, invoked by selecting READ DATA from the main menu and then EDIT DATA from the next menu, provides the means to "tag" any measurement cycle. The data in this tagged cycle is not considered when performing subsequent calculations and is not printed. The data is not deleted from the data file. If saved onto cassette tape, the deletions will not be saved. It should be noted that all data in deleted measurement cycles, i.e. systolic, diastolic, and mean pressures, and heart rate are not used for calculations. It is not possible to tag just one parameter.

## Using EDIT DATA

1. Select READ DATA from the BP MENU and then EDIT DATA. Figure 24 shows the first reading of the sample data as seen using the EDIT DATA program.

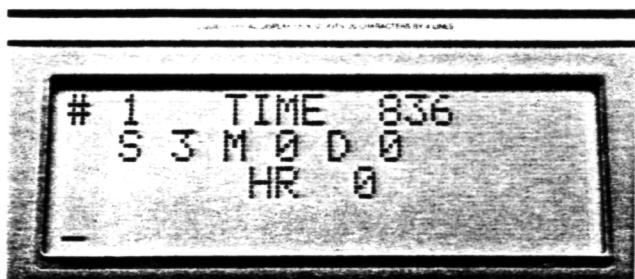


Figure 24. First EDIT DATA.

2. To display the next measurement cycle, press the down-arrow key above the RETURN key. Measurement cycle number two (#2) is displayed (see the sample, Figure 25). The first line displays the reading number (#1), the word TIME, and the military time (838). The second line displays the systolic (S), diastolic (D), and mean (M) pressures. The third line displays the heart rate (HR).



Figure 25. Measurement #2 Displayed.

3. To display the previous measurement cycle, press the up-arrow key above the RETURN key.

### NOTE

*Pressing the shift key with the up- or down-arrow key will move the display ten measurements instead of one.*

4. To tag a measurement cycle, use the appropriate arrow keys to display the cycle you wish to tag. Figure 26 shows measurement #1 as our sample.



Figure 26. Measurement #1 Displayed.

5. To delete a measurement, press the letter D (Delete) key. See Figure 27. The tagged cycle is displayed again but the letter X appears as the first character on the second line. This indicates that this cycle is tagged. It will not be used in calculations nor will it be printed, but the data is retained in memory.

If the memory were saved on cassette tape, the deleted measurement would not be saved.

displayed and the computer will return to the BP MENU.



**Figure 27. Deleted Measurement Display.**

6. To untag the cycle, press the letter R (Retrieve) key. See Figure 28. The cycle is displayed again without the letter X. The data will be displayed and used during calculations.



**Figure 28. Retrieved Measurement Display.**

7. When all editing has been completed, press the RETURN key. CALCULATING AVERAGES will be

## Transferring Data

Measurement data can be stored on the microcassette tape and then transferred to the Station for data analysis. Data can also be moved from the cassette to the POS Computer. Transfer from the POS Computer to the cassette tape is covered under the topic AFTER TESTING. Refer to that section for computer to cassette tape transfer. The following information instructs you how to copy data from the cassette tape to the POS Computer.

### Cassette Tape To POS Computer

1. Insert a data file tape into the tape drive. Select READ DATA (#2) from the BP MENU.
2. Select either READ 1ST TAPE FILE or READ 2ND TAPE FILE from the READ DATA menu. As explained in the section AFTER TESTING, the SAVE DATA program duplicates the data files on a tape to provide information backup in case one file is bad.
3. The computer will rewind the tape, read the file you selected, and then rewind the tape again.
4. The computer will display CALCULATING AVERAGES. Finally, the BP MENU will be displayed.

### Communications

The communications program is under development. You will receive an updated BP MENU program when it is finished. Proper documentation will be included with your updated program.

## CARE AND CLEANING

### Do's and Don'ts

**Don't insert the RAM Pack into either the monitor or POS when the power is on.**

Damage to RAM Pack or interface board may occur.

**Don't remove the RAM Pack from either the monitor or the POS when the power is on.**

Damage to RAM Pack or interface board may occur.

**Don't Overcharge The Batteries**

If you leave the Portable Operating Station battery charger plugged in, eventually you will overcharge the batteries. When the computer's batteries need recharging, it will flash CHARGE BATTERIES. Turn off the power switch and plug in the charging unit for eight hours. If you recharge the POS before you see the message, you will shorten the battery life. Charging the POS for more than eight hours will also shorten the battery life. See Section 3, Operation, Recharging Batteries.

If the batteries fail to hold a charge have the unit serviced by a qualified service personnel.

**Do use only alkaline batteries in the RAM Pack.**

Using carbon type batteries will shorten the testing period and may result in loss of your measurement data. Don't use rechargeable batteries. They may damage the monitor.

**Don't Pull On The Paper When The Printer Is Running**

You may damage the microprinter if you do this. It is

ok to gently pull on the paper when the printer is not printing.

**Do Protect From Extreme Humidity**

Exposure to water or extreme humidity can cause damage.

**Do Keep Out Of Extreme Heat And Cold**

The POS works best in temperatures between 41F and 95F. Storing the POS and Monitor in temperatures outside this range can damage it permanently.

**Do Connect Only To Another POS**

The BP MENU Communications program is written to run only with another POS.

**Do Protect From Physical Shock**

Although the POS suitcase is sturdy, damage may result from dropping it. When shipping the POS to a Service Center, ship it in its original shipping container and protective foam.

### Cleaning

The monitor carrying bag can be cleaned with isopropyl alcohol.

The cuff is machine washable. The microphone and air bladder must first be removed. The bladder can be reinserted by z-folding the bladder and stuffing it into the cuff and then inflating it. Replace the microphone with the label TO ARM toward the inside of the cuff.

The air hose can be cleaned with isopropyl alcohol.

## TROUBLES?

This section contains the error code listing and some troubleshooting information.

The Telephone Modem TEST Switch can be useful to check that the modem is operating properly. To test the modem, simply lift a telephone receiver and flash the switch-hook until there is nothing on the line. Then set the TEST switch to TEST, turn on the modem and

place the receiver in place on the modem. The READY light turns when the modem checks out ok.

### NOTE

*To obtain technical assistance in the mail-in return for repair of your ambulatory monitor or operating station, please call (800) 547-8805 and ask for the Service Support.*

## ERROR CODES

The following list defines the error codes which can be displayed by the monitor.

### E00

Blood pressure could not be detected by auscultatory or oscillometric methods.

### E01

A blood pressure determination was not possible due to excessive noise and/or pressure artifacts.

### E02

A time-out has occurred before a pressure measurement could be taken. This may be due to an air leak in the system, improper cuff placement, cuff not connected securely to monitor, etc.

### E03

A blood pressure measurement was cancelled by the patient. Check for air leaks, improper size of cuff, or cuff not connected to monitor properly.

### E04

Measurement could not be completed within 90 seconds.

### E06

A low battery condition exists and the measurement was aborted. Three letters, "LLL", are displayed in the window and a one second audible alarm is sounded. The doctor should be notified immediately.

### LLL

See E06 above.

## APPLICATION TROUBLES

Following are some hints and kinks gathered from experience. You may find an answer to a problem here. If there is a problem, first check for an error code and see the error code listing above. If there is no error code, check the following listing for suggestions to the problem. If all else fails, call ICR Customer Support.

### **The cuff is very uncomfortable.**

The patient should be still when a measurement is being taken. Movement or a noisy environment may be interpreted as Korotkoff sounds causing the pump to inflate the cuff further.

Driving a car has shown to be a noisy environment. When the patient hears the alarm, he should, if possible,

stop the car. If that is not possible, the patient should cancel the measurement.

### **Measurement data was lost from the computer.**

If you pressed the MENU or BREAK key, you erased the data. Reload it from the RAM Pack or cassette tape. If you did not copy the data onto the cassette tape and the RAM Pack has since been reused, your data is lost.

### **The computer doesn't work.**

Remove the RAM Pack from the interface board slot and press RESET or reset the date/time clock (using control-@). If that fixes it, try a known good RAM Pack. If it doesn't work again, have your POS serviced by a qualified service person.

If RESET or resetting the date/time clock fixed it, you will need to reread the measurement data. If you reset the date/time clock, you will also need to reload BP MENU from microcassette tape.

If it still does not work, and if the screen does not display RECHARGE BATTERIES, try recharging the batteries. If after 8 hours of charging the computer still does not work, have the POS serviced by a qualified service person.

**The RAM Pack will not initialize.**

Remove the RAM Pack batteries. Check the batteries (even if they're new). Wait five minutes and reinstall the batteries or use new ones. Reinitialize the RAM Pack and try it again.

**The monitor screen does not display 000 after the monitor is turned on.**

Remove the RAM Pack batteries and check them (even if they're new). Wait five minutes and reinstall the batteries or use new ones. Reinitialize the RAM Pack. Try it again.

**The RAM Pack gets hot after several hours.**

Remove the RAM Pack from the monitor and remove the batteries. Wait five minutes, then replace the batteries with new ones and reinitialize the Pack. Try using the Pack again.

If this procedure fixes the problem, the RAM Pack is usable, but it should be serviced at the next available time. If the RAM Pack will not work, it should be serviced by a qualified service personnel. It is not usable.

## ACCESSORIES

The following accessories (both supplied and optional) may be ordered from

SPACELABS, INC.  
MONITORING SUPPLIES DIVISION  
20550 PRAIRIE STREET  
CHATSWORTH, CA. 91311  
(800) 423-5037  
(213) 882-9560

### Supplied Accessories

The following accessories are supplied with Portable Operating Station and monitor. Additional quantities of these accessories may be ordered from the above addresses.

Description	Part Number
Procedure Kit .....	305824-001
MC30 Microcassette .....	368996-001
Printer Paper (two rolls) .....	368996-003
Patient Diary .....	368996-005
Hospital Utility Grip .....	368993-001

Cuff Assembly (Standard) .....	T015-0009-00D
Waist Belt .....	T016-0021-00C
Shoulder Strap .....	T016-0022-00C
Monitor Carrying Case .....	T016-0017-00D
Power Cord .....	T161-0138-00

### Optional Accessories

The following optional accessories may be ordered from the above addresses.

Description	Part Number
Microprinter Ribbon .....	368996-002
Alkaline Battery, C-cell .....	368996-004
Single Part Form .....	368996-008
2-part Form .....	368996-009
Cuff Assembly (Small) .....	T015-0008-00D
Cuff Assembly (Large) .....	T015-0010-00D
Cuff w/Bladder (Standard) .....	110961-501
Cuff w/Bladder (Small) .....	110962-501
Cuff w/Bladder (Large) .....	110963-501
Microphone/Hose Assembly .....	T015-0038-00D